



APHIS Evaluation of the Status of the Czech Republic Regarding Classical Swine Fever and Swine Vesicular Disease

**Animal and Plant Health Inspection Service
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Abbreviations

APHIS	Animal and Plant Health Inspection Service
BIP	Border Inspection Post
CFR	Code of Federal Regulations
CSF	Classical Swine Fever
CVO	Chief Veterinary Officer
EC	European Commission
EU	European Union
EU-15	Fifteen EU Member States prior to 1 May 2004 accession
FVO	Food and Veterinary Office of the European Commission
NDCC	National Disease Control Center
OIE	World Organization for Animal Health
SVA	State Veterinary Administration of the Czech Republic
SVI	State Veterinary Institute
SVD	Swine Vesicular Disease

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Executive summary

The Czech Republic submitted requests to the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) in 2004 and 2005 to be considered free of classical swine fever (CSF) and swine vesicular disease (SVD), respectively. Czech officials have not identified specific swine exports to the United States, but requested to be evaluated in conjunction with other new European Union (EU) Member States. Upon receipt of these requests, APHIS initiated an evaluation of the Czech Republic's status with regard to CSF and SVD in order to assess the risk of opening trade.

On 1 May 2004, the Czech Republic and nine other countries became new Member States of the EU. As part of the accession process, the Czech Republic adopted the legislation of the European Commission (EC) regarding animal health, welfare, and identification, including that pertaining to CSF and SVD. These decisions and directives were transposed into Czech law and became the basis for new standard operating procedures by the time of accession. The Czech Republic also adopted the harmonized EC legislation for import, export, and trade of live swine, pork, and pork products.

This report represents APHIS' evaluation of the status of the Czech Republic with regard to the infrastructure and control measures in place for these diseases and includes an assessment of disease surveillance measures, import practices, laboratory capacity, emergency response procedures, and other factors that could influence the risk of disease introduction into the United States. Since a previous APHIS analysis of the EU prior to accession of the 10 new Member States concluded that the EC control measures for CSF are effective (APHIS 2000), the CSF evaluation focuses in large part on the implementation of EC controls in the Czech Republic.

Supporting documentation for this evaluation consists of information provided by the Czech Republic, observations of a site visit team, information from the World Organization for Animal Health (OIE), peer-reviewed articles, reports of missions conducted by the Food and Veterinary Office of the European Commission, and other technical sources. APHIS considered information provided by the Czech Republic before, during, and after the site visit, which was conducted in June 2005. APHIS used all of the information gathered during the evaluation process to identify risk factors that may require mitigation.

This risk analysis was conducted according to OIE guidelines and therefore includes a hazard identification section, a release assessment, an exposure assessment, a consequence assessment, and a risk estimate. The hazards under consideration are CSF and SVD viruses. Based on the release assessment, APHIS has no evidence that either of these hazards currently exist in domestic swine in the Czech Republic: CSF was last reported in 1997 and SVD has never been reported. However, the release assessment concluded that CSF virus is circulating at very low levels in the wild boar population.

Release assessment

CSF virus was last isolated from wild boar in 1999, but serological surveillance has continued to detect CSF antibodies in juvenile wild boar hunted in districts close to the borders with Austria and Slovakia, albeit in decreasing numbers each year. These findings in juvenile animals indicate recent viral transmission; the fact that the number of

juvenile wild boar positive on serological surveillance is decreasing each year suggests that the epidemiological situation is improving.

Nevertheless, CSF virus circulating among wild boar within the Czech Republic poses a risk of exposure of domestic swine. This risk is substantially mitigated by commercial production and biosecurity practices on swine confinement operations such as breeding farms, semen collection centers, and large production units. Production and slaughter systems in the Czech Republic are such that large confinement operations are the most likely source of swine commodities for export to the United States. Consequently, the release assessment concluded that the export risk to the United States associated with low levels of CSF virus circulating in wild boar is low.

However, the release assessment also identified several pathways by which either CSF or SVD virus could be introduced into the Czech Republic from other EU Member States or affected third countries, thereby potentially resulting in risk to the United States in opening trade. Specifically, the following pathways for disease introduction into the Czech Republic are of interest to APHIS: (1) natural movements of wild boar; (2) import and trade of live swine; (3) import and trade of swine products; (4) incoming vehicular and human traffic; and (5) agricultural commodities for personal consumption.

The Czech Republic shares common land borders with countries that APHIS considers regionally affected or of unknown risk for CSF and/or SVD. In addition, the harmonized EC import legislation by which the Czech Republic operates imposes less stringent restrictions on sourcing of imported swine and swine products than does U.S. legislation, enabling Member States to import live swine or swine commodities from potentially affected regions. The Czech Republic also trades on the EU internal common market with other Member States that import live swine or swine commodities from such regions.

However, introduction of CSF or SVD into the Czech Republic by the assessed pathways would only affect export risk to the United States if domestic swine – either breeding animals as in a semen collection center or production swine raised for slaughter – became infected and this infection was not detected prior to export. Again, commercial production and biosecurity practices substantially mitigate the export risk to the United States. Additional mitigation measures may be necessary to restrict sourcing of swine from the Czech Republic for the export process and to prevent commingling of live swine or swine products with those from regions that APHIS regards as affected or of unknown risk for these diseases.

The release assessment concluded that the export risk from the Czech Republic with regard to CSF and SVD is equivalent to that of the 15 Member States comprising the EU prior to the May 2004 accession (the EU-15). Sufficient information is available from the Czech Republic and other EU Member States for APHIS to conclude that there is little substantive difference in the way trade is carried out in these entities. In addition, the Czech Republic has fully implemented EC disease prevention and control measures at a level equivalent to that of the EU-15.

APHIS regards the EU-15 as low risk with respect to CSF and has therefore imposed the import conditions specified in 9 CFR 94.24 for breeding swine, pork, and pork products, and 9 CFR 98.38 for swine semen. Similarly, large portions of the EU are considered by APHIS to be free of SVD, but are subject to the import restrictions specified in 9 CFR

94.13 based on the existence of common land borders with regions not regarded by APHIS as free of these diseases, and/or import of live swine or swine products from regions not considered free of these diseases.

APHIS concludes from this assessment that applying the provisions of 9 CFR 94.13, 94.24, and 98.38 to the Czech Republic would address the majority of the outstanding risk issues identified in the release assessment and result in a level of risk that is equivalent to that portion of the EU that is authorized to export breeding swine, swine semen, and fresh pork to the United States.

Exposure assessment

APHIS assessed the probability of exposure of susceptible animal populations in the United States to CSF or SVD viruses carried by pork or pork products, live swine, and swine genetic material imported from the Czech Republic. This assessment concluded that the probability of exposure of susceptible swine to these viruses via waste feeding was low, based on studies of the of the U.S. waste-feeding sector. Although the unmitigated potential for exposure to infective virus via live swine or swine genetic material was comparatively high, APHIS concluded that the likelihood of exposure of U.S. domestic swine via pork or pork products, live swine, or swine genetic material from the Czech Republic was low. The mitigation measures in 9 CFR 94.24 for horizontal transmission and 98.38 for artificial insemination would further limit the risk of exposure to CSF and (indirectly) SVD viruses.

Consequence assessment

APHIS also assessed the biologic and economic consequences of introducing CSF or SVD viruses into the United States. This assessment concluded that CSF virus has the potential to cause significant distress and suffering in affected animals, whereas SVD infection usually follows a more mild course. The economic costs of control and eradication of these diseases would be substantial and export losses due to restrictions imposed by trade partners on animals and products susceptible to these diseases could run into billions of U.S. dollars. An extensive foreign animal disease outbreak could also result in severe psychosocial effects on farmers and farming communities.

Risk estimate

In summary, although a CSF or SVD outbreak in the United States would likely have severe animal health and economic consequences, APHIS considers the risk of infected live swine or swine commodities entering the United States from the Czech Republic and exposing U.S. domestic swine to be low. This risk is further reduced if the Czech Republic is subject to the same mitigations measures as are specified in 9 CFR 94.13, 94.24, and 98.38 for other EU Member States.

Hazard identification

The hazards under consideration in this analysis are the CSF and SVD viruses.

1. Classical swine fever virus

CSF, also known as hog cholera, is a contagious and economically damaging viral disease of domestic swine and wild boar with worldwide distribution. It is caused by the CSF virus of the family Flaviviridae, genus *Pestivirus* (Wengler et al 1995). CSF virus is quite hardy, being stable between pH 4 and 10 (Depner et al 1992) and also stable at low temperatures (Harkness 1985). The virus would likely remain viable even after carcass maturation, and is unlikely to be destroyed by transport or cold storage. Laboratory confirmation of infection, essential during an outbreak situation, is complicated by the close antigenic relationship of the CSF virus with bovine viral diarrhea virus and border disease virus (Wengler et al 1995).

The incubation period for CSF is 2-14 days (OIE 2005b). The virus multiplies in the epithelial crypts of the tonsils and may be carried to local lymph nodes and into the bloodstream for distribution throughout the body (Trautwein 1988). Blood and all tissues, secretions and excretions of sick and dead animals are sources of virus (OIE 2005b). CSF virus has been recovered from muscle and lymph nodes of infected pigs, and high titers of virus have been isolated from bone marrow (Wood et al 1988). The disease may also be introduced or spread via infected semen (Elber et al 1999).

CSF can spread in an epidemic form as well as establish enzootic infections in domestic swine and wild boar populations. Infection generally spreads directly from pig to pig, but products including fresh, frozen, or cured pork can remain infectious to other pigs via the oral route (Edwards 2000). Imported pig products are frequently implicated in the introduction of CSF virus into previously disease-free regions, primarily through the practice of swill feeding (Fritzemeier et al 2000). Dahle and Liess (1992) demonstrated that the oral infectious dose of CSF virus is very low. Indirect transmission may occur via movement of people, wild animals, and inanimate objects such as live-haul trucks (Elbers et al 2001).

The role of wild boar as a virus reservoir and possible source of infection for domestic swine is well known and epidemiological links between CSF virus infection in wild boar and domestic swine have been reported repeatedly in recent years (Biagetti et al 2001; Laddomada et al 1994). In countries that are free of CSF in domestic swine, epidemics in wild boar are often started by feeding of infected food waste (EC 1999). Abnormal mortality and sometimes obviously sick animals are the first indicators of CSF introduction into a wild boar population (EC 1999).

Four distinct clinical forms of CSF have been described, including acute, chronic, congenital, and mild manifestations (Moennig et al 2003; Paton and Greiser-Wilke 2003). The acute form involves a disease progression of 2-4 weeks and is characterized by high fever, generalized illness, hemorrhagic lesions, immunosuppression with secondary infections, and high mortality. The chronic form may last 30-90 days before death and usually involves older swine or congenitally infected piglets. Congenitally infected piglets may develop symptoms of chronic CSF within 3-6 months, or may never develop symptoms but continuously shed virus. Mild CSF is typically seen only in sows and may

result from exposure to a low virulent strain. Infected sows may show no overt clinical signs but continuously shed virus to their young and to other swine they contact.

2. Swine vesicular disease virus

SVD is a contagious and economically damaging disease of domestic swine and wild boar. The disease has historically been recorded in Hong Kong, Japan, and several European countries; however, in 2004 the disease was primarily limited to Italy and Portugal (OIE 2005b). The SVD virus belongs to the family Picornaviridae, genus *Enterovirus* (Wengler et al 1995). SVD virus is particularly hardy, resistant to pH changes between 2.5 and 12 (Herniman et al 1973), and is very stable under cold conditions (Dawe 1974). The virus is therefore unlikely to be destroyed by the post-mortem decrease in muscle pH that accompanies carcass maturation. SVD virus is also resistant to fermentation and smoking processes, and may remain in hams for 180 days, sausages for over a year, and processed intestinal casings for over two years (OIE 2005b).

The incubation period for SVD is 2-7 days. The intestinal tract is the primary site of infection; however, all tissues contain virus during the viremic period. Blood and feces of sick animals, as well as epithelium from vesicles and vesicular fluid, are good sources of virus. Although SVD virus does not appear to have a tropism for skeletal muscle cells, it is easily isolated from muscle tissue from infected animals after slaughter and bleeding out. SVD may be introduced into a herd by feeding garbage containing infected meat scraps, by introducing infected animals, or by contacting infected feces (e.g., an improperly cleaned truck) (Hedger and Mann 1989; USAHA 1998). After the initial introduction the disease spreads through contact of susceptible pigs with infected pigs and infected feces.

The clinical signs of SVD are easily confused with those of FMD and include fever, sudden lameness, and vesicles with subsequent erosions along the snout, feet, and teats. Morbidity rates may be low throughout a whole herd but high in certain pens. SVD causes essentially no mortality, and recovery usually occurs within 1 week (up to 3 weeks). Persistence of infection with SVD is rare (Lin et al 2001); however, some strains produce only mild clinical symptoms or are asymptomatic, and are detected only through laboratory surveillance (OIE 2005b). For example, a 2002 outbreak of SVD in Italy involved subclinical infection in all but one of 10,312 affected pigs (Brocchio et al 2002).

Release Assessment

A release assessment describes the biological pathway(s) necessary for an importation activity to introduce pathogenic agents into a particular environment and estimates the probability of that occurring (OIE 2005a). This release assessment addresses the 11 factors described under 9 CFR 92.2 for evaluation and regionalization of countries for foreign animal disease status. Risk factors and issues of concern, which may directly or indirectly affect the risk estimate, are identified during this process and discussed at greater length in Section 12, including risk mitigation measures currently existing in the Czech Republic. APHIS evaluated the current status of CSF and SVD in the Czech Republic as well as pathways for disease introduction into the Czech Republic with the potential to impact the assessed status.

1. Authority, organization, and infrastructure of the veterinary services

1.1 Legal authority for animal health activities

The main legal authority for the animal health activities of the official veterinary services in the Czech Republic resides in Act No. 166/1999 concerning veterinary care and amending certain related laws, as amended (the Veterinary Act) (SVA 2004a). The Veterinary Act stipulates the authority and obligations of the official veterinary services with regard to animal transportation and movement control; veterinary controls on import, export, transit, and trade of live animals and animal products; disease surveillance; compulsory notification of reportable diseases including CSF and SVD; control and eradication of infectious diseases; and seizure, depopulation, and compensation in outbreak situations.

The Veterinary Act also stipulates the obligations of animal keepers and private veterinarians with regard to reporting of animal infectious diseases, and ensures access by government officials to private property (SVA 2004a). Noncompliance with the provisions of the Veterinary Act or interference resulting in noncompliance may result in fines ranging from 25,000 – 1,000,000 CZK (1,000 – 42,000 USD).

The provisions of the Veterinary Act are implemented by secondary legislation in the form of Decrees of the Ministry of Agriculture and Methodical Instructions of the State Veterinary Administration of the Czech Republic (SVA). Czech legislation concerning veterinary matters was harmonized with European Commission (EC) legislation approximately six months prior to accession (APHIS 2005a). During APHIS site visits, official veterinarians appeared to be familiar with the provisions of EC and Czech legislation concerning CSF and SVD (APHIS 2005a).

Table 1.1 lists the primary articles of EC legislation pertaining to control of CSF and SVD with the corresponding transposition into Czech legislation (SVA 2004b; SVA 2005b). Commission Decisions and Regulations are directly applicable in all Member States without the need for national implementing legislation, although some Member States choose to do so. In contrast, Council Directives bind Member States to the objectives to be achieved within a certain timeframe and leave the means to the national authorities. Council Directives must be implemented in Czech national legislation.

Table 1.1: Transposition of critical EC legislation regarding CSF and SVD

Disease	EC legislation	Czech legislation
CSF	Council Directive 2001/89/EC of 23 October 2001 on Community measures for the control of classical swine fever (as amended)	(1) Veterinary Act (2) Decree No. 299/2003 on measures for prevention and eradication of contagious diseases and diseases communicable from animals to man
	Commission Decision 2002/106/EC of 1 February 2002 approving a Diagnostic Manual establishing diagnostic procedures, sampling methods and criteria for evaluation of the laboratory test for the confirmation of classical swine fever (as amended)	Methodical Instruction of the SVA No. 7/2003 – diagnostic manual establishing diagnostic procedures, sampling methods and criteria for the evaluation of the results of laboratory tests for the confirmation and differential diagnosis of CSF
SVD	Council Directive 92/119/EEC of 17 December 1992 introducing general Community measures for the control of certain animal diseases and specific measures relating to swine vesicular disease (as amended)	(1) Veterinary Act (2) Decree No. 298/2003 on national reference laboratories and reference laboratories (3) Decree No. 299/2003 on measures for prevention and eradication of contagious diseases and diseases communicable from animals to man
	Commission Decision 2000/428/EC of 4 July 2000 establishing diagnostic procedures, sampling methods and criteria for the evaluation of the results of laboratory tests for the confirmation and differential diagnosis of swine vesicular disease	Methodical Instruction of the SVA No. 8/2003 – diagnostic manual establishing diagnostic procedures, sampling methods and criteria for the evaluation of the results of laboratory tests for the confirmation and differential diagnosis of SVD

Feeding catering waste to swine is prohibited by Czech legislation (APHIS 2005a; SVA 2005c). All producers must register with the SVA and be subject to inspection in order to be eligible for government compensation in outbreak situations. All holdings with more than 50 pigs must be visited annually by an official veterinarian or a private veterinarian under contract with the SVA; official veterinarians inspect about 3% of swine farms annually. Veterinary officials indicated that control of restaurant waste by the public health service limits access by swine producers, but that owners of small farms may be feeding kitchen scraps to their pigs (APHIS 2005a).

1.2. Organization of the official veterinary services

1.2.1 Central competent authority

The Veterinary Act establishes the SVA under the Ministry of Agriculture as the central competent veterinary authority of the Czech Republic (SVA 2004a). The SVA is managed by a General Director who is the Chief Veterinary Officer (CVO) of the Czech Republic. The nine departments comprising the headquarters offices are each headed by a director who reports directly to the CVO (see Figure 1.1). In general, the central SVA performs administrative and supervisory functions necessary to protect animal health and welfare, ensure veterinary hygiene and public health, and implement veterinary border controls. Headquarters personnel are also responsible for managing legal and budgetary affairs, as well as performing internal auditing functions.

The Department of Animal Health and Welfare is responsible for disease monitoring, prevention, control, and eradication; animal welfare activities; animal identification and registration; and crisis management in outbreak situations. In contrast, the Department of Veterinary Hygiene, Public Health, and Ecology is responsible for ensuring the biological and chemical safety of food, conducting veterinary inspections at slaughter, and monitoring rendering and food processing establishments (SVA 2005b)

Figure 1.1: Organizational structure of the SVA

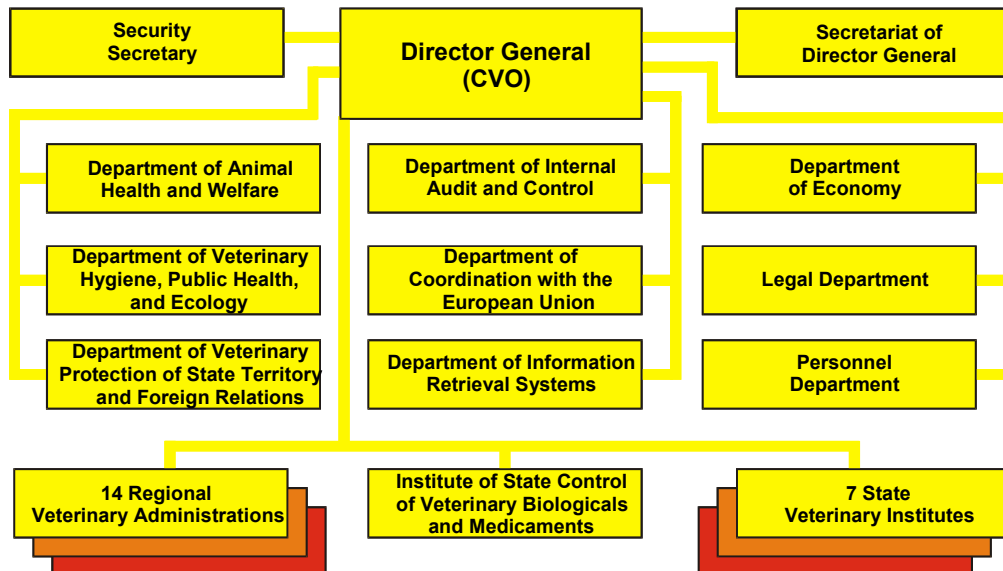
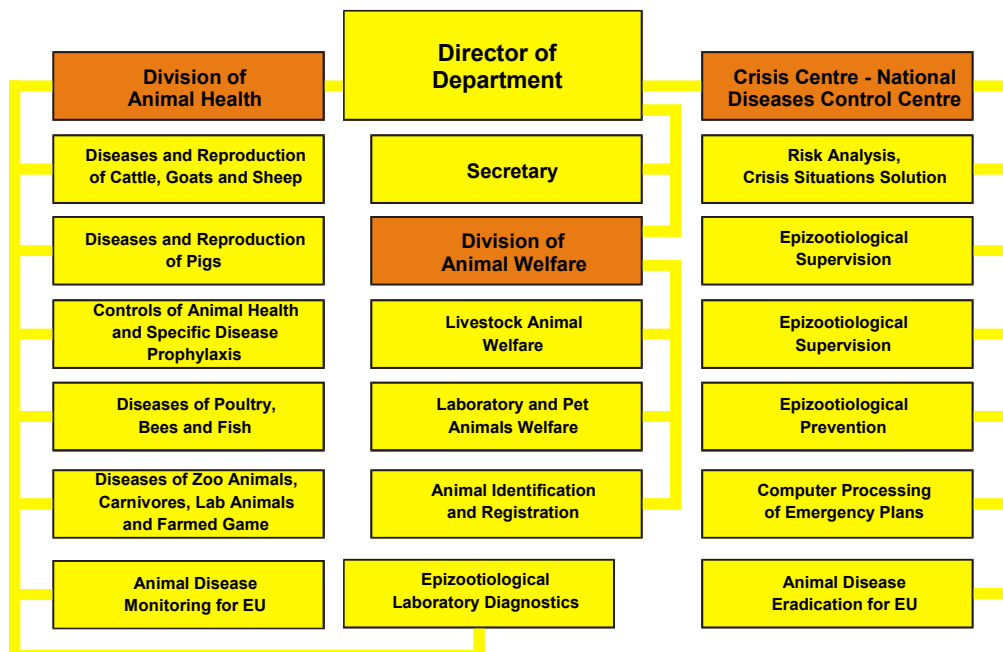


Figure 1.2: Structure of the Department of Animal Health and Welfare

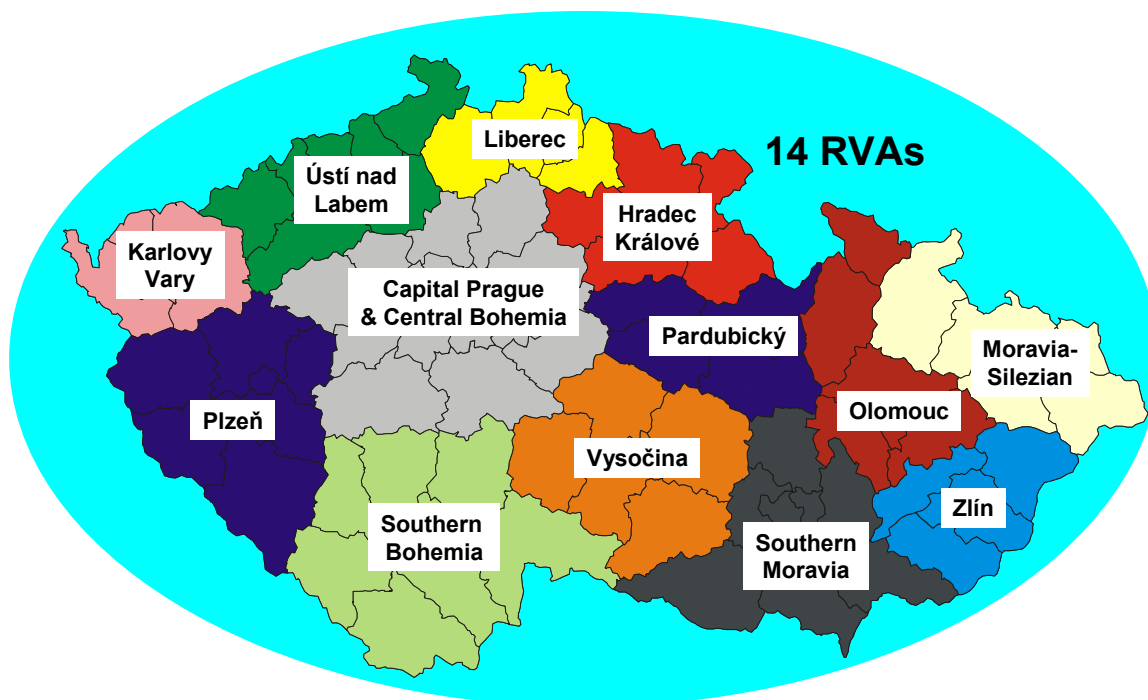


As shown in Figure 1.2, the Department of Animal Health and Welfare contains the National Disease Control Center (NDCC), which is the official animal disease data collection hub of the Czech Republic (APHIS 2005a). The major activities of the NDCC include (1) receiving epidemiological information from all regions, processing the data, and disseminating information; (2) notifying cases of contagious diseases to the OIE, the EC, trading partners, and other international entities; and (3) managing animal health crises. All information on CSF and SVD testing is collected here and shared with the central SVA. The regional SVA offices inform the NDCC monthly of new cases, ongoing cases, and closed cases of all diseases.

1.2.2 Regional veterinary services (administrative unit)

In 2003, the official veterinary services were reorganized into 14 regional offices and 73 district offices (see Figure 1.3) (SVA 2004b; SVA 2005b). Directors of the regional offices are appointed by the CVO and are directly responsible for 3-12 district offices within their region. The organizational structure of the regional and district offices is similar to that of the headquarters SVA, and there is a direct line of command from headquarters through the regional offices to the district offices.

Figure 1.3: Map of regional divisions of the SVA



Although the majority of the veterinary field work is carried out at the district level, a region (*kraj*) is considered by Czech authorities and APHIS to be an “administrative unit,” or the smallest administrative jurisdiction that has effective oversight of normal animal movements into, out of, and within that jurisdiction, and that, in association with national authorities, if necessary, has effective control over animal movements and animal diseases locally (APHIS 2005b). This is the smallest unit to which APHIS could effectively regionalize for disease status under its current regulations.

All official veterinarians are employed at the level of the region, not the district, although most are assigned to district offices (APHIS 2005a). Official veterinarians at the district level are responsible for supervising private veterinarians who are contracted to perform certain official duties. These veterinarians are subsidized by the SVA and must attend monthly meetings with SVA officials, which provides a measure of oversight. In the event of an animal disease outbreak, the regional directors are empowered to take the actions necessary to control and/or eradicate the disease in compliance with national contingency plans and laws.

1.2.4 Border veterinary inspection

The Czech Republic is an inland country surrounded by other EU Member States. The only direct entry point from third countries is the airport Praha-Ruzyně (Prague), which is approved under Commission Decision 2001/881/EC for import of equidae and other live animals, but not for porcine species. This border inspection post (BIP) is also approved for traffic in swine products for human and non-human consumption. Official operation of the airport BIP is under the control of the SVA Department of Veterinary Protection of State Territory and Foreign Relations and the regional office in Prague (APHIS 2005a). Border veterinary inspection is discussed in more detail in Section 7.

1.2.5 Diagnostic laboratory services

The diagnostic laboratory system is composed of seven State Veterinary Institutes (SVI) located throughout the country, as discussed in Section 10 (SVA 2005b). SVI Prague is the national reference laboratory for vesicular diseases such as FMD and SVD, whereas the SVI Jihlava is the national reference laboratory for CSF. The director of each SVI reports directly to the CVO.

1.3 Infrastructure of the official veterinary services

1.3.1 Physical infrastructure

The central, regional, and district SVA offices visited by the site visit team were sufficient for the needs of the veterinary services, including computers with internet and intranet connections (APHIS 2005). Extensive paper records were also kept in most offices. The airport BIP was a new facility, built in 2003. The laboratory facilities were well organized and very well equipped (APHIS 2006a).

1.3.2 Personnel infrastructure

The official veterinary services employ approximately 1,700 people total, of which 770 are veterinarians, 450 are veterinary technicians, and 93 are veterinary assistants (level of training between a veterinarian and a veterinary technician) (APHIS 2005a). The headquarters office has approximately 115 employees of which 44% are veterinarians and 56% are administrative personnel, whereas the regional offices consist of 46% veterinarians, 24% administrative staff, and 30% veterinary technicians/assistants (SVA 2005b). The SVI laboratory system has approximately 414 staff, of which 22% are veterinarians, 29% are administrative staff, and 48% are laboratory technicians. There are also 4 veterinarians on staff at the airport BIP. In 2004 there were approximately 2,450 veterinarians in private practice in the Czech Republic (OIE 2006).

The central SVA provides ongoing training for regional and district SVA officials (APHIS 2005a). Regional officials hold monthly meetings with the district officials at which are discussed current regulations and disease characteristics. Each January the regional office reviews all instructions with district officials and additional meetings are held if new regulations are passed down from the central SVA. Instructions and regulations are also available on the SVA website. Official veterinarians have participated in international training courses on CSF and other diseases (APHIS 2005a).

District SVA officials provide instruction to private practitioners via monthly meetings (APHIS 2005a). The Czech Veterinary Chamber also organizes continuing education courses and practical training for all veterinarians. In addition, the NDCC periodically organizes practical field training on how to deal with suspect cases of foreign animal diseases. SVA officials also discuss biosecurity measures and risk concerns with local producer associations.

National simulation exercises have been conducted in recent years for FMD and highly pathogenic avian influenza, but not for CSF or SVD. Veterinary officials consider the principles to be the same for all such diseases (APHIS 2005a). All simulation exercises incorporate the Czech army and local emergency services. However, the Czech Republic does not have a formal program for training official veterinarians to be foreign animal disease diagnosticians (APHIS 2006a).

1.3.3 Financial resources

All expenses of the SVA come out of the State budget via the Ministry of Agriculture (APHIS 2005a; SVA 2005b). Each district is responsible for its own annual financial planning but can apply for emergency adjustments through the regional SVA if necessary. The EC contributes funding for monitoring of contagious animal diseases, including up to 60% of the cost of CSF monitoring. Such funding is accompanied by requirements for certain actions by the SVA and farmers, including obligations for animal identification, herd registration, and disease reporting. In 2005 approximately 323,360 Euros were allocated for CSF monitoring (SVA 2005b).

1.4 Internal and external audit systems

1.4.1 Internal auditing

An internal audit office at the headquarters level audits the civil service and financial operations of the central SVA (APHIS 2005a). This office also functions to control and audit all levels of the official veterinary service, although the regional SVA offices are also directly responsible for ensuring that the district offices are performing their duties.

1.4.2 External auditing

The Food and Veterinary Office (FVO), which is part of the EC's Health and Consumer Protection Directorate-General, conducted numerous animal health, animal welfare, and food safety inspections in the Czech Republic prior to accession. Although the majority of these reports has not been made public and was not available for this assessment, no derogations with regard to animal health were made at the time of accession.

Commission Decision 98/139/EC provides the authority for post-accession auditing actions necessary to ensure uniform compliance with the provisions of Community

legislation. The scope of auditing of a Member State includes the provisions of any of the agreements on sanitary measures applicable to trade in live animals and animal products with third countries. Under Commission Decision 98/139/EC, the audited Member State must investigate and correct any identified sources of noncompliance within a given timeframe or may face sanctions applied by the EC.

1.5 Discussion

The official veterinary services are hierarchically organized and appear to have clear lines of command and reporting, with considerable autonomy at the district level. The responsibilities of each supervisory position and the departments are well defined, and the departments appear to have sufficient independence to carry out the tasks assigned efficiently. The official veterinary services have sufficient legal authority, personnel, and financial resources to carry out most animal health activities quickly and efficiently. Official veterinarians, particularly at the regional level, appear to be familiar with directly applicable and transposed EC legislation concerning CSF and SVD, and implement the provisions thereof.

However, the official veterinary services conduct inspections of swine farms and monitor compliance with the waste feeding ban at a relatively low level that is likely insufficient to ensure full compliance, particularly on small farms. Waste feeding is arguably the most common route of introduction of CSF or SVD into a susceptible swine population and feeding of household kitchen waste to swine is a common practice among small holders throughout the world. Waste feeding to swine on small holdings is therefore an issue of concern in the Czech Republic, as elsewhere in the world. The impact on the risk of disease introduction into the Czech Republic and export risk to the United States is discussed in Section 12.

2. Disease status in the region

2.1 Classical swine fever

The Czech Republic last reported a CSF outbreak in domestic swine in June 1997 in the Kroměříž district, which lies in the middle of the Zlín region (see Figure 1.3) (APHIS 2005a; OIE 2006). Prior to that, outbreaks occurred in the Břeclav district of the Southern Moravian region in February 1997 and in November and December 1996. The Břeclav district borders on both Austria and Slovakia. The suspected source of the June 1997 outbreak was indirect transmission from wild boar via feed or litter; an outbreak in wild boar was detected in August 1997 approximately 5 km away (APHIS 2005a).

Control measures in domestic swine included destroying all affected herds, establishing surveillance and protection zones, and allowing movement of swine to slaughter and other destinations only after a negative herd test (APHIS 2005a). All herds in the protection and surveillance zones were tested across age groups as follows: (1) less than 20 pigs on the farm = all tested; (2) 20-100 pigs = 20 minimum plus 20% of remaining; (2) over 100 pigs = 20 minimum plus 10% of remaining. Samples from all dead or sick pigs exhibiting clinical signs of CSF were submitted for laboratory testing. The only positive serologic findings were in sows that had been previously vaccinated.

The last reported CSF outbreak in wild boar occurred in November 1999, when virus was isolated from 17 hunted specimens in the Vyškov, Kroměříž, Hodonín, Vsetín, Zlín, and Uherské Hradiště districts (SVA 2005b; OIE 2006). These are first and second tier districts along the border with Slovakia (see Figure 2.1). Numerous positive serologic findings were also reported in wild boar in 1999 (see Figure 2.2); these primarily occurred in districts where CSF virus had been previously isolated from domestic swine or wild boar (APHIS 2005a; SVA 2005b; SVA 2005c).

Figure 2.1: Virology-positive hunted wild boar in 1999

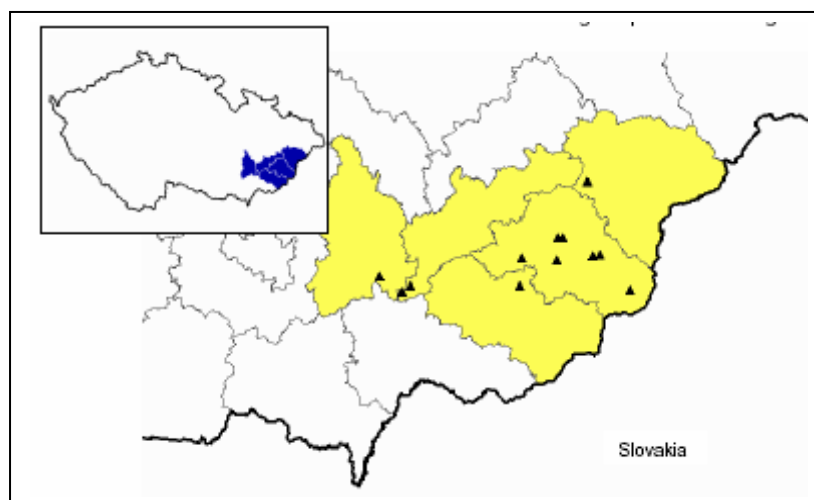
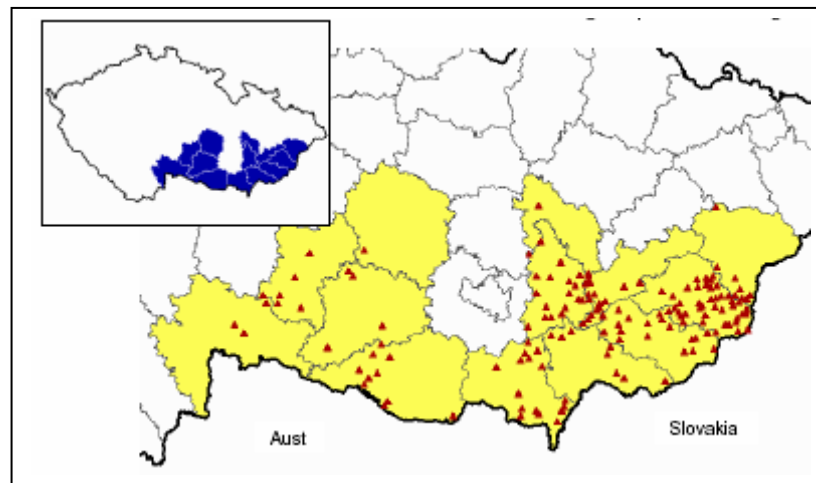


Figure 1.2: Seropositive wild boar in 1999

Control measures for outbreaks in wild boar historically included establishing protection and surveillance zones, effecting a standstill of animal movement, and informing all affected groups of the outbreak (APHIS 2005a). Group hunting was banned in the area but the SVA worked with the hunting associations to increase individual hunting throughout the two zones. All carcasses were inspected and tested by the SVA and then condemned and transported to rendering facilities. Veterinary officials did not know the percentage of the wild boar population hunted as a result of the outbreaks, but estimated that the numbers were greater than in previous years.

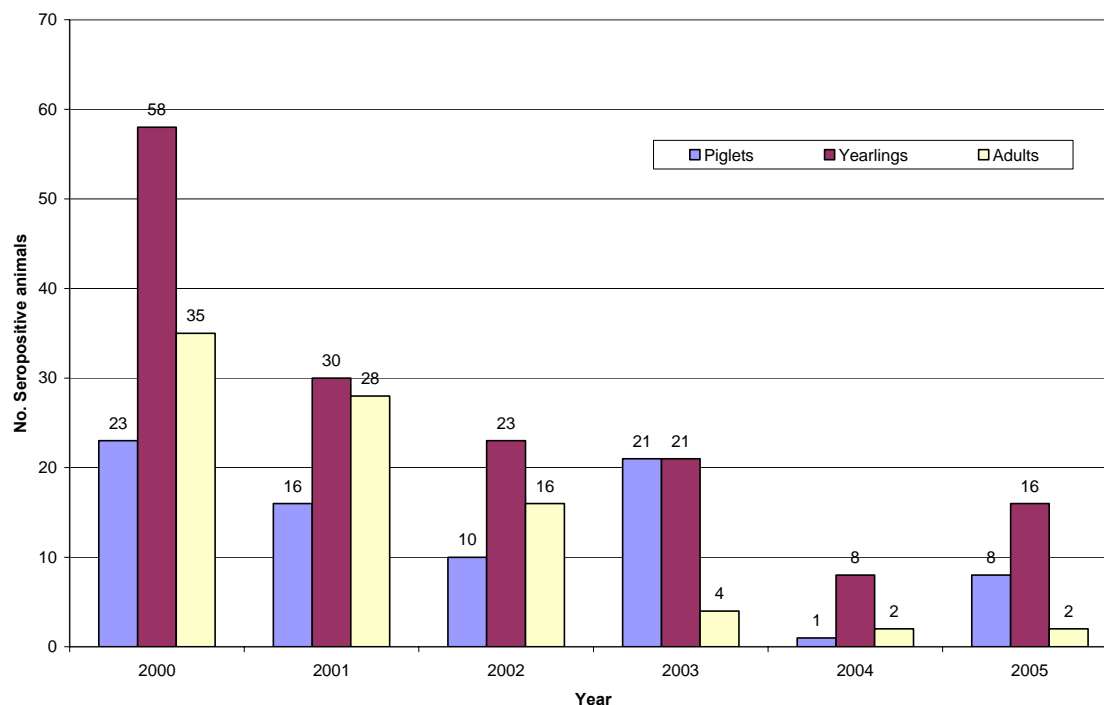
Virus typing studies suggest two distinct epidemiological sources of recent CSF outbreaks in the Czech Republic (Bartak and Greiser-Wilke 2000; APHIS 2005a; SVA 2005b). Isolates from outbreaks in 1990 – 1994 were closely related to a virus subgroup isolated from Austrian wild boar during the same period, whereas the majority of isolates from outbreaks in 1996 – 1999 were closely related to a Slovakian subgroup.

The official veterinary services continue to report decreasing numbers of positive serologic findings in wild boar, primarily in first and second tier districts along the Austrian and Slovakian borders. The number of wild boar hunted has remained relatively constant from year to year (APHIS 2005a; SVA 2005c). Wild boar of all age groups – piglets, yearlings, and adults – have proven positive on serology (SVA 2005c). Virus isolation becomes rare when the incidence of new infection is low because the virus cannot be detected for more than a few weeks following infection (Van Oirschot 1999). In contrast, seroprevalence is detectable at low incidence levels since antibodies can be detected for the lifetime of the animal (Laddomada 1994; Van Oirschot 1999).

Positive serologic findings in juvenile wild boar are generally of particular interest since they indicate recent viral transmission (Rossi et al 2005), except in piglets less than three months of age that may still carry maternal antibodies (Dahle and Leiss 1992; Van Oirschot 1999). Several researchers have suggested using seroprevalence in juveniles to estimate the incidence of CSF infection in the year the individuals were born and thereby track changes in incidence from year to year (Laddomada 1994; Rossi et al 2005). The

positive serologic findings among piglets and yearling wild boar in the Czech Republic indicate ongoing exposure to CSF virus in some segments of the population, although at decreasing incidence. Figure 2.4 summarizes the positive serologic findings by age group; the complete data for 2000 – 2005 are provided in Annex 2. It is not possible to determine from these data which virus subgroups are involved.

Figure 2.4: Positive serologic findings in wild boar by age group 2000 – 2005



2.2 Swine vesicular disease

SVD has never been reported in either domestic swine or wild boar in the Czech Republic (SVA 2005b; OIE 2006).

2.3 Discussion

CSF virus has not been detected in domestic swine since 1997, and SVD has never been reported in either domestic swine or wild boar. CSF virus has not been detected in wild boar since 1999; however, serologic surveillance indicates that the virus is present in segments of the wild boar population along the borders with Austria and Slovakia, albeit at very low and apparently decreasing levels. This reservoir of infection in wild boar poses a risk of exposure of domestic swine as discussed in Section 12.

3. Disease status of adjacent regions

Since accession on 1 May 2004, the Czech Republic is entirely surrounded by EU Member States. It borders to the west with Germany; to the northeast with Poland; to the southeast with Slovakia; and to the south with Austria (see Figure 3.1).

Figure 3.1: Map of the Czech Republic and surrounding regions



3.1 Classical swine fever

3.1.1 Austria

Austria last reported CSF outbreaks in January 2001 and July 1996 in wild boar in the Niederösterreich region, which is located along the southern border of the Czech Republic (OIE 2006). Czech surveillance data suggests that wild boar in Austria introduced CSF into the Czech Republic between 1990 and 1994 (see Section 2). APHIS currently recognizes Austria in 9 CFR 94.9 and 94.10 as a region where CSF is not known to exist in the domestic swine population.

3.1.2 Germany

CSF is endemic in certain segments of the wild boar population in Germany and sporadic outbreaks involving both wild boar and domestic swine are ongoing. At the time this report was written, APHIS recognized all of Germany as free of CSF except certain administrative units (kreis) in the Lands of Brandenburg, Lower Saxony, North Rhine-Westphalia, Rhineland-Palatine, and Saxony-Anhalt. Numerous outbreaks in wild boar, and occasionally domestic swine, have been reported in recent years in the Land of Rhineland-Palatine, which is located in western Germany (OIE 2006).

Hundreds of outbreaks occurred in 2001 and 2002 in both wild boar and domestic swine in the Lands of North Rhine-Westphalia, Lower Saxony, and Saarland, as well as

Rhineland-Palatine. In addition, an outbreak occurred in domestic swine in March 2006 in the Land of North Rhine-Westphalia that was apparently unrelated to the wild boar situation (OIE 2006). Epidemiological investigation of this outbreak was ongoing at the time this report was written.

3.1.3 Poland

Poland reported CSF outbreaks in domestic swine in September 1994 in the territories of the current Lubuskie, Podlaskie, Lubelskie, and Wielkopolskie provinces, none of which border on the Czech Republic (OIE 2006). No CSF cases in wild boar have been reported in recent years; however, an FVO mission carried out in 1997 reported that virus-positive samples were found during routine wild boar monitoring in 1996 (FVO 2001). APHIS was evaluating the CSF status of Poland at the time this report was written.

3.1.4 Slovakia

CSF is endemic in certain segments of the wild boar population in Slovakia and sporadic outbreaks occur in domestic swine as well (OIE 2006). Outbreaks have occurred in domestic swine and/or wild boar in districts of Slovakia along the Czech border, specifically Nové Mesto, Trenčín, and Púchov, which are still restricted by the EC under Commission Decision 2003/526/EC. APHIS was evaluating the CSF status of Slovakia at the time this report was written.

3.2 Swine vesicular disease

The last SVD outbreak in Austria was reported in 1979, in Germany in 1985, and in Poland in 1972 (OIE 2006). SVD has never been reported in Slovakia (OIE 2006). APHIS considers Austria and Germany to be free of SVD under 9 CFR 94.12. Poland and Slovakia were under evaluation at the time this report was written.

3.4 Discussion

3.4.1 Classical swine fever

CSF infection is endemic in segments of the wild boar populations in Germany and Slovakia, and has historically been present in Austria as well. CSF in wild boar has proven very difficult to eradicate and infected wild boar constitute a reservoir for exposure of domestic swine (EC 1999). The known infected wild boar populations in Germany are located at a considerable distance from the Czech border. However, the Czech Republic shares a common land border with regions of Slovakia where CSF infection likely exists in wild boar, which is a risk factor for disease introduction.

3.4.2 Swine vesicular disease

APHIS considers Austria and Germany to be free of SVD, and Poland and Slovakia were under evaluation at the time this report was written. SVD has not been reported in Poland in over three decades and has never been reported in Slovakia. While the potential for introduction of SVD from these countries cannot be ruled out in the absence of a full evaluation, it is reasonable to consider the likelihood low in comparison to CSF.

4. Extent of an active disease control program

4.1 Former OIE List A diseases

At the time of the site visit, Czech veterinary officials considered their country free of all former OIE List A diseases in domestic animals (APHIS 2005a). The Czech Republic is listed by the OIE as free of FMD without vaccination and is considered by APHIS to be free of FMD and rinderpest under 9 CFR 94.1, with restrictions under 9 CFR 94.11¹.

4.2 Discussion

Active disease control programs for CSF or SVD do not exist in Czech Republic, since these diseases have not been reported for many years. Surveillance for these diseases is discussed in more detail in Section 9. The Czech Republic is considered free of FMD and, if found to be free of CSF and SVD as well, would be able to export swine products to the United States with appropriate mitigation measures for these and other swine diseases.

¹ Regions listed under 9 CFR 94.11 are in a special category for FMD because, even though APHIS has determined that the region is free of FMD, one or more of the following conditions occur: (1) the region supplements their national meat supply through the importation of meat from ruminants or swine from regions that are not designated in 9 CFR 94.1 as free of FMD; (2) they share a common land border with regions that are not designated as free of FMD; or (3) they import ruminants or swine from regions that are not designated as free of FMD under conditions less restrictive than would be acceptable for importation into the United States.

5. Vaccination status of the region

5.1 General information

The last vaccination against CSF occurred in 1992; vaccination has been prohibited since that time (SVA 2004b; SVA 2005b). The Czech Republic has never vaccinated against SVD and such vaccination is also prohibited (SVA 2005b). There are no manufacturers of CSF or SVD vaccine in the Czech Republic (SVA 2005b). The Czech contingency plan for CSF, described in greater detail in Section 11, allows for emergency vaccination in an outbreak situation if sanctioned by the EC (SVA 2005b).

5.2 Discussion

Vaccination against CSF and SVD is officially prohibited in the Czech Republic. Since the last vaccination against CSF occurred in 1992, the probability of a vaccine titer interfering with routine CSF surveillance is very low. Any positive result on surveillance testing triggers a comprehensive epidemiological investigation (APHIS 2005a).

6. Separation from adjacent regions of higher risk

6.1 General information

There are no natural barriers separating the Czech Republic from neighboring countries (SVA 2005b).

6.2 Discussion

Without natural barriers, few impediments exist to introduction of CSF or SVD via natural movement of wild boar or, less likely, human traffic. Wild boar are not considered to be migratory in nature, but individual animals are known to travel substantial distances in search of food, during mating season, or in response to hunting or other habitat disruptions. Moreover, CSF is known to exist in wild boar in neighboring countries and regions (see Section 3). Factors influencing the likelihood of disease introduction via natural movement of wild boar are discussed in Section 12.

7. Movement control and biosecurity from higher risk regions

7.1 Border veterinary inspection points

7.1.1 Infrastructure

The Czech Republic is an inland country surrounded by other EU Member States. The only entry point from third countries is the airport Praha-Ruzyně (Prague), which is approved under Commission Decision 2001/881/EC for import of equidae and other live animals (zoo, exotic, pets), but not for ruminant or porcine species. This BIP is also approved for swine products for human and non-human consumption. Official operation of the airport BIP is under the control of the SVA Department of Veterinary Protection of State Territory and Foreign Relations and the regional office in Prague (APHIS 2005a).

The airport BIP was built to EC specifications as described by Annex II of Council Directive 97/78/EC and Commission Decision 2001/812/EC. There are separate sectors for unloading and inspection of live equidae, other live animals, products of animal origin for human consumption, and products of animal origin not for human consumption (APHIS 2005a). The live animal sectors have appropriate facilities for animal restraint and housing; the product sectors have adequate room for offloading, examination, sampling, and storage at either room temperature or refrigerated. There are also facilities for storage of frozen products for human consumption.

The BIP currently receives approximately two tons of products per month (APHIS 2005a). The number of shipments has increased since accession to the EU. Products for import are mainly ornamental fish from Asian countries (five or more shipments per day); also lamb from Australia and New Zealand, beef from Uruguay and Argentina, and semen from the United States. Compliance problems include documents that are not in order or missing, shipments from establishments that are not approved by the EC, and forged documents. Rates of noncompliance have generally declined since May 2004 due to greater familiarity of importers with EC requirements.

The BIP is open 7-9 hours each day with 4 veterinarians on staff, 2 each dedicated to product and live animal inspections (APHIS 2005a). There is no administrative or technical staff. The BIP is fully computerized with an online database for registering consignments and access to the TRACES system. The central SVA informs the BIP by fax of any new legislation related to import controls; all import control legislation is also posted on an SVA website and maintained in hard copy at the BIP. In addition, a manual of procedures provides guidance on the implementation of EC import control legislation.

The central SVA inspects the BIP 3-4 times per year to evaluate the facilities and working procedures, and provides the reports to the regional SVA in Prague, which is responsible for monitoring corrective actions at the BIP (APHIS 2005a). The FVO also conducts periodic audits, most recently in November 2005 (FVO 2005).

At the time of the APHIS site visit the airport BIP appeared to be operating well within the scope of available resources (APHIS 2005a). The veterinary inspectors appeared knowledgeable of the pertinent EC and Czech legislation and were confident in their job skills (APHIS 2005a). Veterinary authorities indicated that the inspection staff relies heavily on the Customs Service for import checks on pets (APHIS 2005a).

7.1.2 Biosecurity

All employees must go through a clean room with changing facilities when entering or exiting any sector (APHIS 2005a). Each sector is cleaned and disinfected after unloading and reloading, as are the storage rooms if used. BIP officials are responsible for supervising the destruction of catering waste from international means of transport. Airport authorities handle the actual waste collection, storage, and removal, and BIP officials inspect the facilities quarterly. Regarding road and rail transportation, EC and Czech legislation requires that all live-haul trucks and rail cars be cleaned and disinfected at the point of destination. Such vehicles from third countries must be accompanied by a certificate indicating that they were disinfected prior to loading. No disinfection measures are in place for vehicular traffic at border crossings without veterinary inspection.

7.2 Import controls

7.2.1 Legislative controls

Live swine, pork, pork products, and genetic materials are harmonized commodities under EC legislation, which means that the requirements for import from third countries are standardized across all of the Member States. Council Decision 79/542/EEC lists third countries from which live animals and fresh meat may be imported into the EC. Other legislation specifies the conditions under which meat products, meat preparations, wild game meat, and genetic material may be imported from third countries. Pertinent legislation has been transposed into Czech law by means of numerous Decrees of the Ministry of Agriculture (SVA 2004a).

Council Decision 79/542/EC permits importation of live swine from Switzerland, Chile, Canada, New Zealand, and Iceland. APHIS recognizes all of these countries as free of SVD, with or without restrictions under 9 CFR 94.13², and all but Switzerland as free of CSF, with restrictions on Chile under 9 CFR 94.24. APHIS considers any region affected until the agency has completed an evaluation of the CSF risk of that region. Evaluation of disease status is initiated at the request of veterinary authorities in the foreign country, which Switzerland has not done. APHIS therefore has little knowledge of the CSF surveillance and reporting practices in that country, except that it reported CSF in wild boar in 1999 and is bordered by Member States with endemic CSF infection in wild boar.

Council Decision 79/542/EC also allows importation of fresh pork and pork products derived from domestic swine from Belarus and several other regions that APHIS has not evaluated and therefore regards as unknown risk for CSF or SVD, and also permits some of these regions to export fresh meat from wild boar to EU Member States. However, slaughter establishments, cutting plants, and cold storage units in third countries must be inspected and approved for export to the EC. The inspection process is stringent,

² Regions listed under 9 CFR 94.13 are in a special category because, even though APHIS has determined that the region is free of SVD, one or more of the following conditions occur: (1) the region supplements its national pork supply with fresh, chilled, or frozen pork from regions that are not designated in 94.12 as free of SVD; (2) it shares a common land border with regions that are not considered to be free of SVD; or (3) it has trade practices that are less restrictive than are acceptable to the United States. The text of 9 CFR 94.13 is provided in Annex 1.

although the EC may grant provisional approval prior to inspection if the exporting country provides sufficient guarantees that the required conditions are met.

Commission Decision 2002/613/EC specifies the import conditions for swine semen, including authorized third countries, approved semen collection centers, animal health conditions, and model veterinary certificates. Import of swine semen is permitted from approved collection centers in Canada, New Zealand, the United States, and Switzerland. Swine semen collection centers must be approved by the EC in accordance with Council Directive 90/429/EEC, which was amended by Commission Decision 1999/608/EC to introduce more stringent biosecurity measures in response to the 1996-97 CSF outbreaks in domestic swine involving two semen collection centers.

Under the amended regulations, swine semen collection centers must be inspected by official veterinarians of the exporting country at least twice per year. Swine admitted to a semen collection center must originate from a herd that is not situated in an area restricted due to disease in domestic swine and must be quarantined for at least 30 days prior to entry. In the case of Switzerland, boars must test negative for CSF in the 30 days preceding quarantine and, to maintain approval, routine testing for CSF must be carried out on 25% of the animals in the center every 3 months or on all animals leaving the center within 1 year of admission. All animals must be tested at least once while at the center and at least every 12 months if their stay exceeds 1 year.

7.2.2 Certification

EC certification requirements for import of live swine and swine products from third countries are generally comprehensive with respect to OIE guidelines and must be signed by an official veterinarian of the country of origin. Commission Decision 2004/212/EC lays out model veterinary certificates for live swine and fresh meat from domestic swine and wild suidae. Model veterinary certificates for embryos, semen, meat products, and related commodities are provided in other Commission Decisions.

The specific certificate used depends on the commodity for export, the exporting country and, in the case of live animals, the purpose for which they are exported (breeding, production, or direct slaughter). BIP inspectors can download country and commodity specific certificates from a website maintained by the EC (VetLex).

For live animals, an official veterinarian must certify that the exporting region is free of FMD, CSF and/or SVD as appropriate, that the swine have remained in the region at least 3 months (slaughter animals) or 6 months (breeding or production animals) prior to export, and that they have not been exposed to any imported cloven-hoofed animals in the 30 days prior to export. The veterinarian must also certify that the swine have not been vaccinated, have remained at a designated holding or assembly center for 40 days prior to export, and that no outbreaks have occurred within a 20 km radius in the preceding 40 days. In addition, live swine from Switzerland, Chile, and Iceland must test negative for CSF and SVD in the 30 days preceding export.

An official veterinarian must certify similar statements regarding disease freedom for meat and meat products exported to the EU. Some regions must provide additional certification regarding waste feeding to domestic swine. One provision requires laboratory testing for CSF of fresh meat from feral swine, but this provision is not

currently applied to any region. For swine semen, an official veterinarian of the exporting country must certify that the semen originated from donor boars in an approved collection center, located in a region free from FMD, CSF, and SVD for at least 12 months without vaccination (Commission Decision 2001/613/EC).

7.2.3 Veterinary inspection

Veterinary inspection and laboratory analysis protocols for swine and swine products follow EC requirements as described in Council Directives 91/496/EEC, 96/43/EC 97/78/EC, as implemented by the Veterinary Act and a number of related Decrees of the Ministry of Agriculture (APHIS 2005a).

Under EC requirements, the common veterinary entry document (CVED) must be used for pre-notification of incoming shipments and submitted to the inspection post at least one working day prior to entry. All consignments intended for import are entered into the Customs system, which is used to identify the consignments requiring a CVED. A recent FVO mission noted that pre-notification was provided for about 60% of consignments and that the remainder is notified after arrival; occasionally the information provided for pre-notification was incomplete (FVO 2005).

Once a shipment arrives, there are three stages of control for both live animals and products: (1) a document check to confirm that the health certificate and other documentation are correct according to EC requirements and have been signed by an official veterinarian of the exporting country; (2) an identity check or visual confirmation of correct ear tags, chips, tattoos, or codes; and (3) a general physical examination with a percentage of the shipment singled out for a more thorough examination.

All incoming consignments are subject to document and identity checks (APHIS 2005a). Products are examined to ensure that they are properly identified and that the country and exporting establishment are listed as approved by the EC. Physical checks are made on 1-5% of consignments and samples are taken from approximately 1% of the consignments subject to a physical check, to monitor for residues, pathogens, and contaminants occurs (APHIS 2005a; FVO 2005). Veterinary officials indicated that physical checks focus on countries with a lower animal health status than the Czech Republic (APHIS 2005a).

If inspectors suspect an infectious disease, the consignment can be rejected or quarantine issued at either the BIP or, in the case of live animals, at the place of destination (APHIS 2005a). If a former OIE List A disease is suspected, the consignment would be held at the BIP pending destruction via rendering. There have been no suspicions of former List A diseases since accession (APHIS 2005a). A recent FVO report noted that confirmation of rendering could not be fully correlated with the incoming consignment; however, Czech authorities subsequently indicated that this issue had been resolved (FVO 2005).

If the veterinary inspection is satisfactorily completed, an official veterinarian completes and signs the CVED, then passes it to the Customs Service (APHIS 2005a). The original CVED accompanies the shipment to the point of destination, where additional spot checks may be performed in accordance with Council Directive 90/425/EEC. If the shipment is refused, the appropriate information is entered on the CVED and all other EU BIPs are electronically notified of the actions taken.

7.3 Transit and transshipment controls

Transit and transshipment of products between third countries is allowed under EC legislation provided that there are no import restrictions for the commodity on the source country. These products generally undergo a document check and identity check at the point of entry, but no further unloading or alteration of the cargo occurs while in the Czech Republic (APHIS 2005a). A recent FVO mission found that the Customs Service used a separate system to track consignments for transit or transshipment that was not able to identify consignments of veterinary interest (FVO 2005). Customs also did not require that a CVED be presented for third country transshipments. Whether or not veterinary checks were performed therefore depended on the information provided by the importer, constituting a risk that some consignments could evade necessary veterinary inspection. The Czech Customs Service subsequently indicated that they are modifying their information systems to facilitate veterinary inspections (FVO 2005).

7.4 Controls on intra-Community trade

Trade in live swine and swine products within the EU is primarily governed by a series of Council Directives that were transposed into Czech legislation prior to accession. An official veterinarian performs a physical examination and any required sampling, completes the required paperwork, certifies the health certificate, and supervises the loading and unloading of animals. The shipment is entered into TRACES and the server informs the point of destination as well as any border crossing points. An official veterinarian at the point of destination confirms the arrival.

Council Directive 90/425/EEC allows for spot checks to be carried out at the points of origin and destination to ensure that consignments are in compliance with the guarantees provided by the health certificates. Czech officials indicated that all breeding swine older than 3 months of age from EU Member States with endemic CSF infection, where intra-community trade is allowed according to regionalization principles, must undergo serologic testing within one month of arrival.

As an EU Member State, the Czech Republic is free to engage in intra-Community trade with any other Member State as governed by the transposed Directives. All live animals and animal products, including semen and embryos, must be accompanied by the appropriate certificate as specified in EC legislation. Intra-Community trade in swine and swine products, including semen and embryos, from CSF-affected regions of the Member States of Germany, Slovakia, France, and Luxembourg is prohibited under Commission Decision 2003/526/EC, as amended. Intra-Community trade in swine and swine products from SVD-affected regions of Italy is also prohibited.

7.5 Volume and type of imports

The Czech Republic has historically received live swine primarily from the EU-15, most notably Germany and France (see Annex 3) (GTA 2006). Import numbers from 1999-2003 ranged from 284 – 2,588 head per year. In 2004, imports of live swine increased to over 9 thousand head in response to market changes associated with accession (GTA 2006). Imports from Germany increased from 11% to 48% of the total and Slovakia gained approximately 9% of the market share. However, the Czech Republic remains a

net exporter of live swine. Exports from 1999 – 2003 ranged from 22.5 – 65.6 thousand head per year, and almost 187 thousand head were exported in 2004 (GTA 2006).

In contrast, the Czech Republic is a net importer of pork meat. From 1999 – 2003, pork imports ranged from 13.5 – 28.5 thousand tons per year, primarily from EU-15 countries such as Germany and Denmark (GTA 2006). The Czech Republic also imported pork from other countries, most notably Hungary and Poland. Pork exports during the same time period averaged $\frac{1}{3}$ to $\frac{1}{2}$ of the import tonnage (GTA 2006). Pork imports increased 22% in 2004 to 62.5 thousand tons, with exports at only 13.7 thousand tons. Imports from Germany increased almost three fold from 10.3 – 27.9 thousand tons.

APHIS recognizes the EU-15 as a low-risk region for CSF under 9 CFR 94.9 and 94.10 that is subject to the conditions described under 9 CFR 94.24³ for pork, pork products, and breeding swine, and 98.38⁴ for swine semen. APHIS also recognizes Hungary and the EU-15 countries (except certain regions of Italy) as free of SVD under 9 CFR 94.12, with restrictions as described under 9 CFR 94.13⁵. APHIS was evaluating the CSF and SVD status of the new EU Member States that are not considered free of these diseases at the time this report was written. However, APHIS has not evaluated many of the third countries from which the Czech Republic has imported live swine and therefore regards them as unknown risk for CSF and SVD.

7.6 Veterinary control of passenger traffic

Per Czech officials, most border crossing points for passenger traffic and local transport into the Czech Republic are controlled by the Customs Service, without veterinary inspection per se (APHIS 2005a). At all border crossings, the Customs Service is responsible for checking personal luggage and detecting illegal imports. X-ray equipment is used to scan personal luggage but sniffer dogs are not used to detect products of animal origin (APHIS 2005a; FVO 2005). Czech officials indicated that there is substantial local traffic across the border from neighboring Member States that is subject to Customs inspection (APHIS 2005a).

Commission Regulation 745/2004, which is directly applicable to all Member States, dictates that posters to promote public awareness of prohibited meat, milk, and meat and milk products must be prominently posted at all border crossings. Under this Regulation, personal consignments of meat, meat products, milk or milk products from the Faeroe Islands, Greenland, Iceland, Liechtenstein, and Switzerland with a combined total weight not exceeding 5 kilograms are allowed, as well as personal consignments of these commodities from Andorra, Norway, and San Marino. The site visit team observed

³ 9 CFR 94.24 restricts the sourcing of pork, pork products, and breeding swine to regions where CSF has not been known to exist, and prohibits commingling with such commodities from CSF-affected regions. The full text of 9 CFR 94.24 is provided in Annex 1 of this document.

⁴ 9 CFR 98.38 restricts the sourcing of swine semen to semen collection centers approved by the national veterinary services of the exporting country, and restricts the sourcing and commingling of donor boars. In addition, the regulations stipulate that donor boars be isolated for 30 days and tested for CSF prior to entering the collection center, and the semen held for 40 days after collection while all boars are observed for signs of CSF. The full text of 9 CFR 98.38 is provided in Annex 1 of this document.

⁵ See footnote on page 26.

posters detailing these restrictions at the airport BIP (APHIS 2005a). APHIS has not evaluated many of these countries and considers them of unknown risk for CSF and SVD, although none have reported an outbreak of these diseases in recent years, if ever (OIE 2006).

A recent FVO report indicated that Customs officials were aware of their obligation to intercept products of animal origin, but were not clear on the specific provisions of Commission Regulation 745/2004 with regard to countries and products (FVO 2005). The Customs Service has the authority to seize illegal products of animal origin; approximately 8-10 kilograms per day are either confiscated or voluntarily abandoned by passengers (APHIS 2005a). All seized products of animal origin are documented and a copy provided to the BIP. However, the FVO mission found that there was no system in place to ensure safe disposal of these commodities due to legal difficulties in assigning responsibility for disposal. Czech officials subsequently indicated that this issue was resolved through an amendment to the Veterinary Act (FVO 2005).

7.7 Discussion

The BIP visited by APHIS in 2005 is an impressive facility that appeared to be largely underutilized. The EC standards for BIP approval are high and the approval and auditing processes are strict. The veterinary inspection staff appeared knowledgeable of import control legislation cited in the handbook and confident in implementing inspection procedures. Both electronic and paper records were well organized and readily accessible. Biosecurity measures were adequate in the absence of an active outbreak.

A few deficiencies were noted in the system of import controls, including gaps in the implementation and enforcement of EC requirements for passenger checks and disposal of confiscated products of animal origin (APHIS 2005a; FVO 2005). The Customs Service performs a significant role in preventing illegal imports of animal products and Customs officers must be thoroughly familiar with the provisions of pertinent EC legislation. Veterinary personnel need full access to Customs databases for incoming consignments in order to identify eligible consignments for inspection. Czech officials indicated that these issues are being addressed through cooperative agreements and ongoing training.

Based on the information presented here, the following pathways for disease introduction are of interest to APHIS: (1) import and trade of live swine; (2) import and trade of swine products; (3) incoming vehicular and human traffic; and (4) agricultural commodities for personal consumption. These pathways are discussed briefly below and summarized in more detail in Section 12.

7.7.1 Import and trade of live swine

EC legislation imposes less stringent restrictions on sourcing of imported swine than do APHIS requirements, which could result in a comparatively greater risk of CSF introduction into the Czech Republic. However, APHIS considers intra-Community trade in live swine on the internal common market to pose a greater risk of introducing CSF infection into the Czech Republic, particularly in light of the substantial increase in live swine traded to the Czech Republic from Germany and Slovakia since accession. Although standard control measures limit the movement of live swine from restricted

areas within the EU, CSF outbreaks have occurred outside of established control zones within Member States where CSF is endemic in wild boar, posing a risk to the common and export markets until detected.

Risk mitigation measures currently in place include a mandatory observation period and veterinary inspection prior to shipment, certification of disease status by an official veterinarian, isolation procedures with veterinary spot-checks at the point of destination, and serological testing of breeding swine from Member States with endemic CSF infection in wild boar. Imported swine also undergo veterinary inspection at the port of entry into the Czech Republic. Depending on the extent of clinical signs, the observation periods and veterinary inspection may greatly increase the likelihood of disease detection.

EC certification requirements also reduce the risk of disease introduction and are generally comprehensive with regard to international standards. Country and commodity specific certificates are readily available to veterinary inspectors on the internet and the inspectors appeared familiar with the content and governing regulations. EC import policies and the restricted scope of SVD infection worldwide limit the risk of importing this disease into the Czech Republic. Similarly, APHIS considers the risk of introducing SVD into the Czech Republic via intra-Community trade in live swine to be low.

7.7.2 Import and trade of swine products

Harmonized EC legislation permits importation of fresh pork and pork products, as well as fresh meat from wild boar, from third countries that APHIS does not recognize as free of CSF or SVD (i.e., countries of unknown risk). EC legislation also permits importation of swine semen from Switzerland, which APHIS has not evaluated and regards as unknown risk for CSF. Intra-Community trade in most swine products is prohibited from regions affected by CSF or SVD, which substantially limits the risk to the common market. However, CSF outbreaks occurring outside of established control zones pose a risk to the common and export markets during the time that they remain undetected.

Risk mitigation measures currently in place concerning swine products include approval of establishments for export or trade, veterinary certification requirements, and veterinary spot-checks at the point of destination. Imported products must also originate from authorized third countries and undergo veterinary inspection at the point of entry. Although veterinary inspection of imported swine products at the port of entry is comprehensive, testing for CSF or SVD is generally not required. Consequently, veterinary inspection would likely detect irregularities in documentation or identity, but the physical examination would not detect virus if present.

EC certification requirements for pork, pork products, and swine genetic material are generally comprehensive with regard to international standards and must be signed by an official veterinarian of the country of origin. The certificate used depends on the commodity for export and includes specific guarantees for products from certain countries. Approval of exporting establishments substantially limits exports from authorized third countries.

7.7.3 Incoming vehicular or human traffic

As discussed in Section 3, the Czech Republic shares land borders with Germany and Slovakia, both of which have regions restricted by the EC due to CSF outbreaks in

domestic swine. Some of the restricted regions in Slovakia are along the border with the Czech Republic. There is considerable local passenger traffic to and from these countries, which could contribute to introducing CSF into the Czech Republic.

In accordance with EC regulation, the Czech Republic and other Member States require disinfection of live-haul trucks after each transport (APHIS 2005a). Czech officials indicated that, if a new outbreak were reported in a neighboring region, biosecurity measures would be put in place such as disinfecting the undercarriage of all vehicles. Additional biosecurity measures would be enacted for airline passengers from affected regions in the event of an outbreak further abroad.

7.7.4 Agricultural commodities for personal consumption

EC legislation permits personal consignments of products that could carry live CSF or SVD virus from countries that APHIS has not evaluated and considers of unknown risk for these diseases. The majority of border crossings are controlled by the Customs Service, without veterinary control per se, although signs indicating prohibited items and prominently placed amnesty bins may decrease the amount of illegal products unintentionally carried across the border.

8. Livestock demographics and marketing practices in the region

8.1 Swine and wild boar demographics

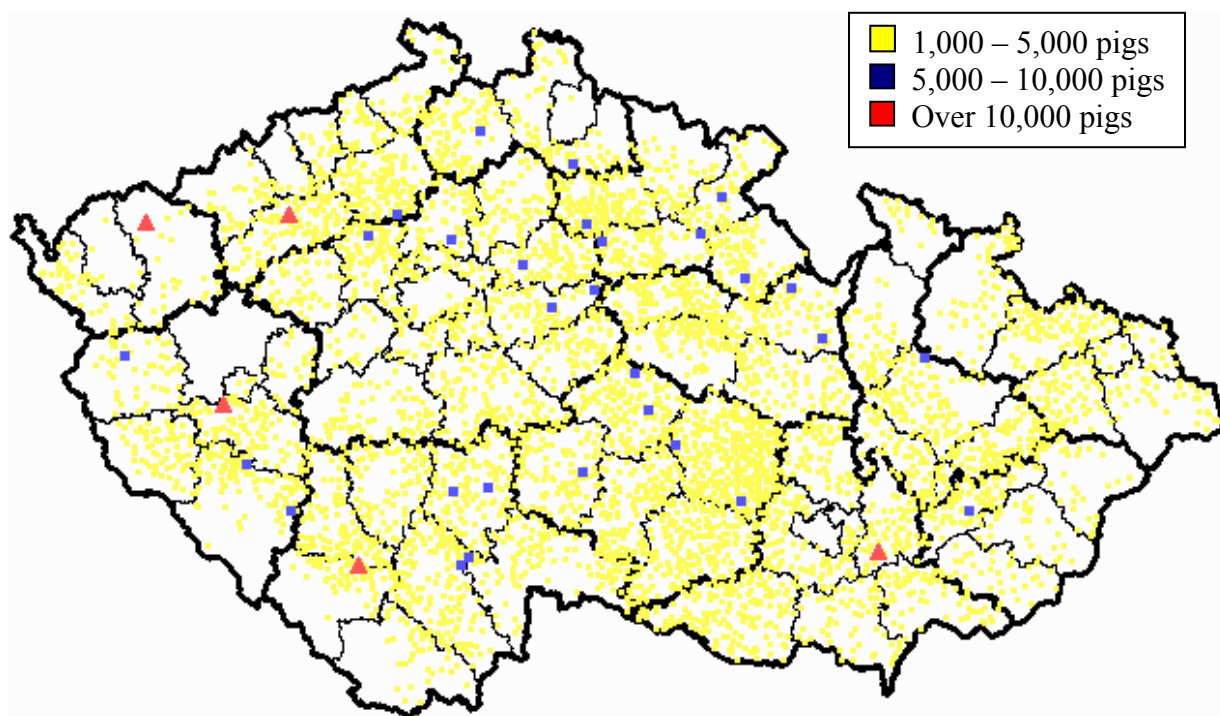
In 2005 there were an estimated 2.9 million pigs in the Czech Republic, of which 233 thousand were sows, a decrease of approximately 8% from April 2004 (SVA 2005b; SVA 2005c). The number and density of swine in each region is given in Table 8.1 (SVA 2005c), and the location of breeding farms with over 5,000 pigs is shown in Figure 8.1 (SVA 2005b). According to Czech officials, these large farms are the most likely to export to the United States (APHIS 2005a).

Table 8.1: Porcine demographics per region (SVA 2005c)

Region	Total area (km ²)	Hunting area (km ²)	No. Pigs	Pig density per km ²	No. Wild boar	Wild boar density per km ²
Prague/Central Bohemia	11,512	9,787	415,646	36.11	7,183	0.73
Southern Bohemia	10,057	8,450	348,209	34.62	6,699	0.79
Plzeň	7,561	6,188	212,974	28.17	6,953	1.12
Karlovy Vary	3,314	2,444	42,349	12.78	2,219	0.91
Ústí nad Labem	5,335	4,251	116,604	21.86	4,149	0.98
Liberec	3,163	2,343	43,166	13.65	1,677	0.72
Hradec Králové	4,758	3,775	209,737	44.08	2,294	0.61
Pardubice	4,519	3,820	193,783	42.88	2,960	0.77
Vysočina	6,925	6,161	391,482	56.53	2,257	0.37
Southern Moravia	7,065	5,722	433,761	61.40	3,632	0.63
Olomouc	5,159	4,125	215,185	41.71	2,287	0.55
Moravia-Silezian	5,535	4,643	104,796	18.93	2,352	0.51
Zlín	3,964	3,534	149,142	37.62	1,830	0.52
Total	78,867	65,243	2,876,834	36.48	46,492	0.71

The Southern Moravia, Central Bohemia, and Vysočina regions have the greatest number of domestic swine; the Southern Moravia and Vysočina regions also have the greatest swine density when using total land area within a region to calculate (SVA 2005c). In contrast, the Central Bohemia, Southern Bohemia, and Plzeň regions have the greatest number of wild boar, with the greatest density in the Plzeň, Karlovy Vary, and Ústí nad Labem regions when using the hunting area within a region to calculate.

Most swine producers have few pigs but much of the swine production comes from the larger operations (5,000 – 10,000 pigs). Veterinary officials indicated small swine producers generally keep pigs indoors, and that most of the larger farms are confinement operations with restricted access (APHIS 2005a). The site visit team noted biosecurity measures on larger swine operations such as maintaining perimeter fencing, limiting or excluding vehicular traffic onto the farm, limiting entry of nonessential personnel and visitors, and requiring a change of clothing when entering the production areas. Some farms allow their employees to raise pigs of their own (backyard herds).

Figure 8.1: Location of larger swine operations (SVA 2005b).

8.2 Animal identification system

Legal authority for animal identification and holding registration is given by Act No. 154/2000 on the improvement, breeding and registration of livestock and on the amendment of some related laws, as amended (the Breeding Act). This Act came into force for swine producers in April 2002, and is further supported by Decree No. 136/2004 laying down details concerning identification and registration of animals and the registration of holdings and persons stipulated by the Breeding Act.

A central database is maintained by the Czech-Moravian Breeders Society (CMBS) under the supervision of the Ministry of Agriculture (APHIS 2005a). Each holding is given a unique 8-digit number: the first 2 digits of the holding number indicate the region and the remaining 6 digits denote a particular holding. For swine, the holding number is too long to use as a tattoo, so a “transfer bridge” has been implemented linking the holding number with a 4-digit number used as a tattoo.

All swine producers are obliged to register their holding(s) and animals except for backyard farms with only one pig. Farmers theoretically could not register, but would not be able to sell animals or move them without identification, and would not be compensated in the event of a disease outbreak. Animal owners are obliged to send data on births, purchases, sales, and deaths to the CMBS central database each month and update their own herd register, which is kept on the farm. This register must be submitted to an official veterinarian upon request during any on-farm inspection.

Animal identification and holding registration inspections are carried out by two entities, the SVA and the Czech Breeding Inspectorate (CBI), which is also under the Ministry of Agriculture. The Ministry of Agriculture sends a list of farms to each entity. Farmers are controlled primarily by the CBI, whereas slaughterhouses/rendering plants are controlled

by the regional SVA. Inspections occur annually on approximately 3% of holdings; these include a check of the tags or tattoos, comparison of the holding register and the CMBS database, and comparison of the number of reported versus actual animals on the holding. Compliance is variable (APHIS 2005a).

8.3 Internal movement controls

Health certificates are required for interregional movement within the Czech Republic in accordance with the Veterinary Act (APHIS 2005a; SVA 2005b). No health certificate is required for movement within a region unless going to a slaughterhouse, exhibition, or assembly center. Private veterinarians can sign certificates for movement to slaughter and can initiate certificates for other movements; however, the latter must be signed and stamped by an official SVA veterinarian as well. Copies of health certificates are kept at the district level.

8.4 Discussion

Small holdings predominate in the Czech Republic, which presents a challenge in terms of monitoring and enforcing compliance with the ban on waste feeding, and implementing and maintaining a national swine identification system. However, the staffing at the regional level is sufficient to maintain a reasonable level of premises inspections, and the inspection process is thorough. Good herd registration and swine identification systems are in place; the current system would most likely capture movement to slaughter but relies heavily on reporting by the seller and purchaser for capturing transactions within a region. Potential underreporting of animal movements could hinder the epidemiological investigation in an outbreak situation.

The likelihood of introduction of CSF or SVD viruses by direct or indirect contact with wild boar or other routes is greater on small farms than on large swine operations, due to the relative laxity of biosecurity practices. Pigs on smaller holdings are generally less protected and interaction with wild boar is possible, considering the distribution and overlap of the two species. In addition, employees of some of the larger operations may have small swine farms of their own. If the small herd becomes infected, the employee could theoretically transmit the virus to the larger operation via a vehicle or clothing. Transmission by this route would require a lapse in other biosecurity measures, such as showering or clothing changes, on the confinement operation.

These factors potentially increase the risk of disease introduction onto small farms and, in some instances, onto larger operations as well. Exports to the United States will likely be derived from the larger confinement operations, most of which are closely monitored by the official veterinary services. Biosecurity measures on the majority of these farms are sufficient to prevent direct or indirect exposure to wild boar and substantially limit the likelihood of virus introduction on a vehicle or clothing.

9. Disease surveillance in the region

9.1 General information

A program for surveillance and monitoring of CSF in both domestic swine and wild boar has been in force for several years. A national surveillance plan is also in place for SVD in domestic swine, but not in wild boar (SVA 2005a; SVA 2005b). Testing is financed through the Ministry of Agriculture budget each year; CSF testing is subsidized by the EC (APHIS 2005a; SVA 2005b). The official veterinary service works with the hunting associations to ensure access to wild boar for testing. Surveillance results forwarded from the regions are compiled by the NDCC.

9.2 CSF surveillance

9.2.1 Domestic swine

The national CSF surveillance program primarily relies on serologic testing of boars and sows at slaughter (SVA 2005b; APHIS 2005a; APHIS 2006a). Other surveillance includes testing of imported breeding swine from third countries and EU Member States with endemic CSF that are allowed to trade under regionalization principles, within one month of arrival. In addition, breeding boars are tested prior to admission to a semen collection center and then annually while in the center. Samples are taken by official veterinarians.

Table 9.1: Summary results of CSF surveillance 1999 – 2005

Year	Domestic swine				Wild boar			
	CTB-ELISA		Virus Isolation		CTB-ELISA		Virus Isolation	
	Tested	Positive	Tested	Positive	Tested	Positive	Tested	Positive
1999	36,181	0	34	0	11,157	0	11,266	17
2000	20,820	0	68	0	9,617	160	9,085	0
2001	22,737	0	25	0	11,349	94	11,440	0
2002	17,987	0	13	0	9,998	51	9,970	0
2003	30,494	0	3	0	9,339	55	9,645	0
2004	20,451	0	2	0	11,449	11	11,566	0
2005	9,954	0	3	0	10,384	26	10,208	0

The percentage of swine tested at slaughter in each district is determined by the SVA based on the epidemiological situation in wild boar. No CSF surveillance is required in districts that have not detected CSF virus or antibodies in wild boar. If CSF antibodies are detected in wild boar in the district, 50% of boars and sows are tested at slaughter, with up to 100% of selected consignments tested. If CSF virus was detected in wild boar, surveillance would be conducted as described in Section 11.

Summary results of CSF surveillance in domestic swine from 1999 – 2005 are shown in Table 9.1; no confirmed positive tests have been reported (SVA 2005b; APHIS 2006a). There have been several field investigations of suspicious cases of CSF in recent years,

none of which has resulted in confirmation (APHIS 2006a). Surveillance in wild boar has remained relatively constant, whereas surveillance in domestic swine peaked in 2003 in preparation for accession to the EU.

9.2.2 Wild boar

A CSF surveillance plan for wild boar is prepared by the SVA and approved by the Ministry of Agriculture annually (SVA 2005c). The 2005 plan called for testing of 10% of hunted wild boar throughout most of the Czech Republic, as well as all wild boar found dead (SVA 2005c; APHIS 2005a). One hundred percent of hunted wild boar in districts bordering Slovakia and Austria are tested, and 50% in selected adjacent districts. In districts where CSF antibodies have been detected in wild boar, 50% of hunted wild boar are tested during the 6 months following the last antibody findings and 25% are tested during the next 6 months. In addition, 25% of hunted wild boar in adjoining areas selected by the SVA are tested during the initial 6-month period after antibody detection.

If CSF virus were found in wild boar, 100% of hunted wild boar from the affected district would be testing during the 6 months following the last positive virus finding, and 50% would be tested during the next 6 months (SVA 2004b; APHIS 2005a). In addition, 50% of hunted wild boar in adjoining areas selected by the SVA would be tested during the initial 6-month period following antigen detection.

Juvenile boars can be hunted all year (representing about 90% of the annual kill), but adult boars can only be hunted from August 1st – January 15th (APHIS 2005a). The SVA works with the various hunting associations to ensure access to wild boar. In addition, a monetary reward is paid for reporting a wild boar found dead (1,000 CZK = 42 USD) and for providing samples from a hunted wild boar (300 CZK = 13 USD).

Hunters are responsible for identifying boar with a yellow bracelet tag at the time of kill and filling out the accompanying documentation (APHIS 2005a). Each bracelet tag has a unique identification number. In districts where 100% sampling of wild boar is required, hunters are also responsible for taking the blood samples at the time of kill using specially designed plastic tubes. Official veterinarians at inspection points take samples of kidney, spleen, and tonsils or lymph nodes for CSF, and samples for trichinella.

Summary results of CSF surveillance in wild boar from 1999 – 2005 are presented in Table 9.1 (SVA 2005b; APHIS 2006a). As noted in Section 2, CSF antibodies continue to be detected in wild boar of all age groups in first and second tier districts along the borders with Austria and Slovakia. No virus-positive results have been reported since 1999.

9.3 SVD surveillance

SVD surveillance is carried out in domestic swine throughout the country; all surveillance is based on serologic testing at slaughter. From 2000 – 2002, 25% of breeding boars and 3% of sows in each shipment from an individual farm were tested at slaughter using a virus neutralization test (SVA 2005a). Beginning in 2003, all slaughtered boars and 3% of breeding sows per shipment were tested using an ELISA test; serum positive on the ELISA is retested using virus neutralization (SVA 2005a; APHIS 2006a).

Summary results of SVD surveillance from 2000 – 2005 are presented in Table 9.2 (SVA 2005a; APHIS 2006a). Per veterinary officials, all positive virus neutralization tests were traced back to the herd of origin and found to be singleton reactors; no clinical signs were observed, and all pigs on the farm were tested with no further positive results (APHIS 2006a). No suspicious cases of SVD have been reported from the field in recent years, and veterinary officials could not estimate even qualitatively the prevalence of vesicular conditions in the field (APHIS 2006a).

Table 9.2: SVD surveillance in domestic swine 2000 – 2005

Year	ELISA		Virus neutralization	
	Total	Positive	Total	Positive
2000	-	-	6,668	-
2001	-	-	5,613	1
2002	-	-	15,925	-
2003	13,623	32	2,132	1
2004	10,523	33	749	4
2005	9,523	18	148	0

9.3 Discussion

9.3.1 Classical swine fever

The risk-based targeted sampling schemes for CSF surveillance in domestic swine and wild boar appear sufficient to detect an outbreak of the disease. The official veterinary service is very aware that an index case of CSF in domestic swine would likely occur from contact with infected wild boar. Wild boar are widely distributed throughout the country, but surveillance results appear to indicate that the prevalence of CSF infection is very low and declining. Considerable incentive is provided for hunters to participate in CSF surveillance in wild boar.

Most of the surveillance is based on serology for antibodies to the CSF virus, as is common throughout the world. Since antibodies occur late in CSF infection, serological surveillance would likely miss an early infection (e.g. first 21 days). Similarly, passive surveillance in the field is likely sufficient to detect overt clinical signs of CSF, but detection may be delayed in the case of moderate or low virulence strains. These factors influence the timeliness of outbreak detection and hence the export risk to the United States, as discussed in Section 12.

9.3.2 Swine vesicular disease

Ample serologic surveillance is conducted for SVD in domestic swine. SVD antibodies are long-lasting; even though mild infections could be missed clinically, the current level of serologic surveillance would likely reveal the historical presence of SVD. The Czech Republic does not conduct surveillance for SVD in wild boar; however, SVD has never been reported in wild boar in the country.

10. Diagnostic laboratory capability

10.1 General information

The diagnostic laboratory system is composed of seven SVIs located throughout the country; since the Czech Republic is a small country, samples can quickly be driven to one of three regional laboratories that participated in CSF and SVD testing. APHIS personnel visited the SVI Jihlava and the SVI Prague. Both laboratories are accredited by the Czech Accreditation Institute (CAI), which in turn is recognized by the International Laboratory Accreditation Cooperation that harmonizes laboratory practices globally. Both laboratories are ISO 17025 certified and quality assurance is ensured by the CAI. Standard operating procedures are in place for each diagnostic procedure and closely follow OIE guidelines. Both laboratories have participated in 'ring tests' to gauge how well they are performing the tests, with good results (APHIS 2006a).

10.2 Classical swine fever

SVI Jihlava is the national reference laboratory for CSF, among other diseases (SVA 2005b; APHIS 2006a). There are 128 staff members, of whom 25 have a university degree (12 veterinarians) and 50 are trained as laboratory technicians. CSF testing is also performed by SVI Prague and SVI Olomouc; each laboratory covers about one third of the country for sample submission. The Jihlava and Prague facilities do serology and virus isolation, while SVI Olomouc only performs serology. Any suspects on serology or other tests performed by the Prague and Olomouc laboratories are sent to SVI Jihlava for confirmatory testing.

SVI Jihlava performs the following tests for CSF:

1. Serology for monitoring: Antibody (Ab) ELISA using two commercial test kits, Ceditest CSFV by Cedi Diagnostics and IDEXX HerdChek ELISA Test Kit.
2. Serology for confirmation: Neutralization peroxidase linked assay (NPLA).
3. Virus isolation (VI) in PK-15 cells with immunoperoxidase to stain antigen.
4. Antigen detection: Antigen (Ag) ELISA using the commercial CHEKIT HCV-Ag ELISA produced by Bommeli Diagnostics and now owned by IDEXX.
5. Reverse transcriptase polymerase chain reaction (RT-PCR): SVI Jihlava has both a group RT-PCR to detect pestiviruses and a specific RT-PCR to detect nucleic acid sequences of the E2 gene of CSF virus.
6. Additional tests like direct fluorescent antibody testing on cryostat tissue sections can be performed but are rarely done now due to adoption of Ag ELISA and PCR.

CSF reference strains used as positive controls for NPLA, VI and PCR are obtained from the OIE CSF Regional Reference Laboratory in Hanover, Germany. SVI Jihlava has the competence to confirm a CSF diagnosis but isolated viral strains would be submitted to the Hanover laboratory for sequencing and phylogenetic analysis to aid in molecular epidemiology.

10.3 Swine vesicular disease

SVI Prague is the national reference laboratory for SVD and vesicular diseases (SVA 2005b; APHIS 2006a). There are 110 staff members, of whom 35 have a university degree (19 veterinarians) and 42 are trained as laboratory technicians. SVD testing is also done by SVI Jihlava and SVI Olomouc; again, each laboratory covers about one third of the country for sample submission. The Jihlava and Olomouc laboratories only do serology and no virus isolation since a bio-safety level three (BSL-3) laboratory is required. SVI Prague has a BSL-3 unit in their laboratory and is therefore responsible for conducting any testing that requires handling of live virus. Any suspects on serology or other tests performed by the Jihlava and Olomouc facilities are sent to SVI Prague for confirmation.

SVI Prague performs the following tests for SVD:

1. Serology for monitoring: Ab ELISA using a commercial test kit, the Ceditest SVDV by Lelystad (Cedi Diagnostics), and the virus neutralization (VN) test using the UK'72 SVD virus obtained from the OIE FMD World Reference Laboratory (WRL) in Pirbright, United Kingdom.
2. VI in IBRS-2 cells.
3. Antigen detection: Ag ELISA using reagents and methodology from the OIE FMD WRL in Pirbright.

VI has not been done in the past 3 years because there has been no indication to do so (APHIS 2006a). SVI Prague has plans to introduce a RT-PCR for SVD in the future. They have the methodology for doing the Antigen Complement Fixation Test, but do not perform it. Consequently, although SVI Prague can do a preliminary diagnosis of SVD using the above tests, any positive tests would be sent to the WRL in Pirbright for confirmation. No samples have been sent in recent years.

10.3 Discussion

SVI Jihlava and SVI Prague laboratories were clean, structurally sound, well organized, and filled with the latest laboratory equipment, often provided by the EC (APHIS 2006a). Both laboratories have well-trained scientific, technical, and administrative staff. Samples in the laboratory could be easily tracked from receipt to final diagnosis and computer entry. Security is excellent, and there is little likelihood that SVD or CSF could be accidentally carried out of a laboratory.

SVI Jihlava provides a full range of diagnostic tests for the diagnosis and confirmation of CSF. Tests have all been validated and include well-regarded commercial test kits used in many countries and tests developed in-house that are performed using standard methodology. Excellent quality control and quality assurance programs are in place. APHIS concludes that an index case would be diagnosed by this laboratory if proper samples at the proper stage of infection were submitted.

SVI Prague provides a moderate spectrum of diagnostic testing for SVD. Tests have all been validated and include well-regarded commercial test kits used in several countries and tests developed in-house that are performed using standard methodology. The BSL-3 unit has all the necessary controls to prevent escape of the SVD virus. SVI Prague has the

competence to make a presumptive diagnosis of SVD, although samples would be sent to Pirbright for confirmatory testing and molecular epidemiology.

11. Emergency response capacity

11.1 General information

The Czech Republic has in place contingency plans and supporting legislation to control and eradicate CSF and SVD outbreaks (SVA 2005b; SVA 2005c; APHIS 2005a). The contingency plans conform closely to the provisions of EC legislation, and the control measures for these and other former List A diseases are similar in many regards. Central elements include (1) the creation of Disease Control Commissions at the central and regional levels that act as advisory bodies during the outbreak response, and (2) activation of regional Expert Teams that conduct the epidemiological investigation.

The NDCC is the main entity responsible for coordinating and managing the emergency response, and also for notifying the OIE, the EC, and trading partners of disease outbreaks and the actions taken. SVA officials at the regional and district levels are responsible for carrying out emergency measures in the event of suspicion or confirmation of CSF or SVD, in accordance with the provisions of the contingency plans. Contingency plans are meticulously prepared by each district and include all relevant orders and instructions, as well as detailed information on the farms in the area (APHIS 2005a). This information is updated regularly and all updates are stamped and dated by an SVA official.

All of the contingency plans follow a stamping out policy that calls for destruction of animals on the affected premises with burial or incineration of the carcasses. All live animals, animal products, and genetic material which moved off the affected premises during the time between disease introduction and detection of the outbreak must be traced and destroyed. Protection and surveillance zones of 3 km and 10 km radius from the affected premises, respectively, are established and movement of live animals, animal products, and genetic material is suspended until the restrictions are lifted.

11.2 Classical swine fever

The emergency response policies and regulations formulated by the SVA reflect control measures established in Council Directive 2001/89/EC and Commission Decision 2002/106/EC. The contingency plan for CSF was approved by the EC under Commission Decision 2004/431/EC; legal authority for the prescribed action is provided by the Veterinary Act and other legislation (SVA 2005b). A model CSF contingency plan serves as a template for drawing up contingency plans at the regional and district levels.

The model contingency plan and supporting legislation detail measures to be taken in case of suspicion or confirmation of CSF on a holding, in a slaughterhouse, at a livestock market, or in a means of transport, including the organization of the response effort (APHIS 2005a; SVA 2005b; SVA 2005c). The contingency plan also details procedures for destruction of animals and carcass disposal, indemnity and valuation of animals, cleaning and disinfection of affected premises, diagnostic procedures and approved laboratories, and the principles of emergency vaccination. Plans are also in place in case of confirmation of CSF infection in wild boar (SVA 2004b).

EC and Czech regulations allow removal of CSF restrictions in protection zones as early as 30 days after completion of preliminary cleaning and disinfection measures on the

infected holding (21 days in surveillance zones). Measures are lifted after clinical examinations and serology indicate that the pigs remaining in the zones are free of CSF.

11.3 Swine vesicular disease

The emergency response policies and regulations formulated by the SVA reflect control measures established in Council Directive 92/119/EEC and Commission Decision 2000/428/EC (SVA 2005b; APHIS 2005a). Legal authority for the prescribed actions is provided by the Veterinary Act and other Czech and EC legislation. A model SVD contingency plan serves as a template for drawing up contingency plans at the regional and district levels. EC approval is not required for SVD contingency plans.

The model contingency plan and supporting legislation provide measures to be taken in case of suspicion or confirmation of SVD on a holding, including the organization of the response effort, chain of command, destruction of animals and carcass disposal, indemnity and valuation of animals, cleaning and disinfection of affected premises, and approved laboratories (SVA 2005b; APHIS 2005a). There are no provisions for emergency vaccination.

11.4 Financial provisions

All emergency measures related to animal health are financed by the State budget through a fund maintained by the Ministry of Agriculture (SVA 2005b). Owners of animals killed on the authority of an official veterinarian are compensated in accordance with the provisions of the Veterinary Act (SVA 2005b). Funding comes from the State budget and the EC; the latter entity provides partial indemnity in case of an outbreak of certain diseases, including CSF and SVD. Council Decision 90/424/EEC describes the conditions under which the EC would support a financial contribution for emergency control and eradication of CSF or SVD, which are covered in the Czech contingency plans and supporting legislation.

11.5 Discussion

The contingency plans for CSF and SVD are comprehensive and reflect control measures developed and promulgated by the EC. Equally important, the official veterinary service members, particularly at the regional and district levels, are familiar with the provisions of the contingency plans and the actions required of them in the event of suspicion and/or confirmation of CSF and SVD infection. Training and national simulation exercises as discussed in Section 1 aid in developing and maintaining the ability to quickly detect and contain these diseases.

APHIS is concerned that 30 days following a CSF outbreak is insufficient time to ensure that an area where an outbreak has occurred is no longer affected by the disease. CSF has recurred in several areas of the EU shortly after EC restrictions were removed from those areas and the movement of swine commenced. For example, in December 2001 a CSF outbreak was confirmed in Osama, Spain, 22 days after release of EC movement restrictions and 83 days after depopulation on the affected holding (APHIS 2004a). Similarly, a CSF outbreak in August 2002 in Luxembourg was epidemiologically linked to an outbreak that occurred in June 2002 (APHIS 2004a). The August outbreak occurred 27 days after release of EC movement restrictions and 56 days after depopulation.

These observations suggest that 30 days may be an insufficient duration for restrictions. APHIS addressed this concern for the EU-15 in a previous regulation by establishing a process which would not allow swine, swine products, or semen from an area affected with CSF in domestic swine to be exported until 6 months after the last affected premises was cleaned and disinfected (APHIS 2006b).

12. Discussion of identified risk factors

12.1 Existing risk factors

The preceding 11-factor assessment identified wild boar within the Czech Republic as a potential source of exposure of domestic swine to CSF virus (*see* Sections 2 and 9). The virus has not been detected in wild boar since 1999; however, CSF antibodies continue to be found in juvenile animals, indicating an ongoing source of infection. Since CSF virus cannot be detected for more than a few weeks following infection, virus isolation becomes rare when the incidence of new infection is low. However, serological prevalence in juvenile wild boar can be used to track changes in incidence from year to year. The fact that the serological prevalence is decreasing each year, while the number and age distribution of wild boar hunted remains relatively constant, suggests that the epidemiological situation is improving.

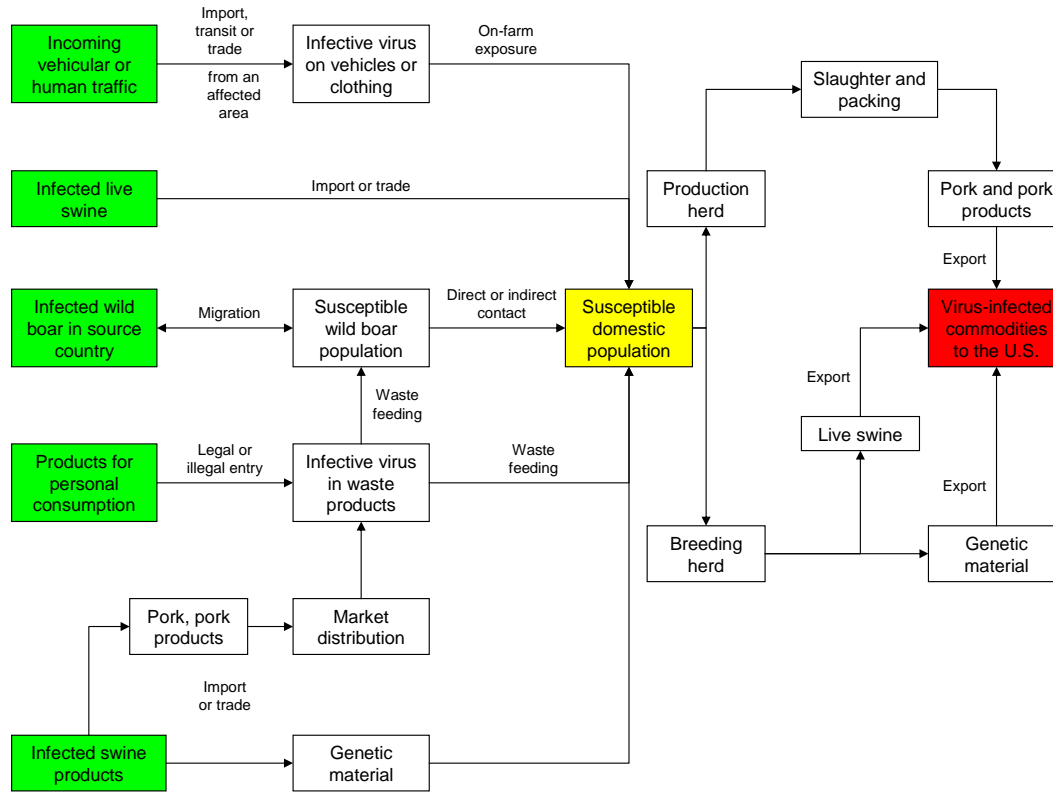
Nevertheless, CSF virus circulating among wild boar within the Czech Republic poses a risk of exposure of domestic swine. However, the risk of direct or indirect exposure is substantially mitigated by commercial production and biosecurity practices on swine confinement operations such as breeding farms, semen collection centers, and large production units (*see* Section 8.1). Exposure to wild boar is more likely on small farms with limited biosecurity, although the tendency towards indoor farming limits the potential for contact. Production and slaughter systems in the Czech Republic are such that large confinement operations are the most likely source of swine commodities for export to the United States. Consequently, APHIS concludes that the export risk to the United States associated with low levels of CSF virus circulating in wild boar is low.

12.2 Pathways for disease introduction

The preceding 11-factor assessment also identified five main pathways by which CSF or SVD could be introduced into the Czech Republic from other EU Member States or third countries, resulting in exposure of a domestic swine population (*see* Figure 12.1). However, introduction of these diseases into the Czech Republic by these pathways would only affect export risk to the United States if a susceptible domestic swine population became infected and this infection was not detected prior to export. The timeframe for detection of a disease incursion depends on a number of factors, including characteristics of the disease agent, surveillance practices, diagnostic capabilities, and the disease recognition capability of animal caretakers and veterinarians.

As discussed under the hazard identification section, some forms of CSF and SVD are difficult to detect in live animals or on post-mortem examination without laboratory testing. For example, carrier sows that were exposed to low virulence CSF strains are capable of shedding virus for substantial periods of time without clinical signs. Similarly, subclinical SVD infection is common, although the period of virus shedding is generally short and persistent infection is rare. The ongoing training discussed in Section 1.3.2 aids in passive surveillance for CSF and SVD by increasing the disease recognition capability of animal caretakers and veterinarians. However, detection of these diseases could be delayed if diagnosis is based on overt clinical signs.

Figure 12.1: Pathway assessment for virus introduction and subsequent export



Active surveillance for CSF and SVD in domestic swine, and CSF in wild boar, appears sufficient to detect the presence of the disease (*see* Section 9), and is well supported by the diagnostic laboratory system (*see* Section 10). Surveillance in wild boar is strengthened by positive incentives for hunter participation. However, serological surveillance for antibodies to CSF would likely miss an early infection, since antibodies occur relatively late (around 21 days). Although passive surveillance could overlook early infection with a moderate or low virulence strain, thereby delaying the time to detection, the current level of serological surveillance would likely reveal the historical presence of CSF or SVD.

APHIS concludes from this discussion that detection of a CSF or SVD incursion in domestic swine could take weeks or even months, under certain circumstances. There would therefore be a period of time between virus introduction and outbreak detection during which infected animals and products could be presented for export to the United States. Physical inspection of individual animals is sufficient to detect clinically affected animals prior to live export, slaughter, or collection of genetic material. However, such inspection is unlikely to detect subclinical or persistent infection.

As noted in the hazard identification section, CSF and SVD viruses may remain viable through carcass maturation, transport, and storage, and may be present in genetic material as well. Consequently, if CSF or SVD is introduced into a domestic swine population in the Czech Republic, the potential exists for it to remain undetected long enough for

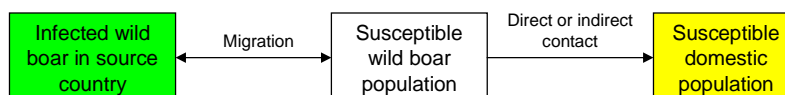
export of infected live swine, pork, pork products, or genetic material to the United States. Although APHIS considers the probability of this scenario occurring to be relatively low, it cannot be entirely disregarded. Consequently, the likelihood of disease introduction via the pathways identified in the previous sections resulting in exposure of a susceptible domestic animal population is examined below.

12.2 Natural movement of wild boar into the Czech Republic

12.2.1 Central risk issue

Infected wild boar migrating from neighboring affected regions could introduce CSF or SVD virus into the Czech Republic. As shown in Figure 12.2, direct or indirect contact with infected wild boar could spread the disease to domestic swine, creating the potential for export of infected live swine or swine products to the United States.

Figure 12.2: Pathway for disease introduction via migrating wild boar



12.2.2 Summary discussion

The likelihood of introducing CSF or SVD into the Czech Republic via migration of infected wild boar from surrounding regions depends primarily on the disease status of wild boar in the neighboring regions and the extent to which natural barriers prevent their movement into the Czech Republic.

As noted in Section 3, APHIS considers Austria and Germany to be free of SVD; although Poland and Slovakia were under evaluation at the time this report was written, SVD has not been reported in Poland for over three decades and Slovakia has never reported this disease. APHIS therefore regards the risk of introducing SVD virus into the Czech Republic via migration of wild boar from potentially affected neighboring regions as very low, particularly considering the limited worldwide distribution of this disease.

In contrast, Germany and Slovakia both have endemic CSF infection in segments of the wild boar populations. Outbreaks in Slovakia have been detected in regions directly abutting the Czech Republic, and there are no natural barriers to prevent wild boar movement between these countries (*see* Section 6). However, in the event of a CSF incursion via wild boar, the risk of exposure of domestic swine is mitigated by the same factors discussed in Section 12.1. APHIS therefore concludes that the export risk to the United States associated with this pathway is low.

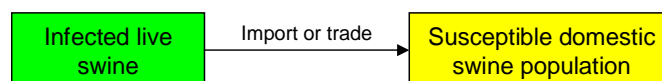
12.3 Import, transit, or trade of infected live swine

12.3.1 Central risk issue

Infected live swine may enter the Czech Republic legally through import from third countries or intra-Community trade, or illegally via smuggling from neighboring countries (*see* Figure 12.3). Legally imported live swine may be intended for breeding,

production (i.e. fattening and slaughter), or direct slaughter. APHIS considers the risk of illegal entry of infected live swine to be low.

Figure 12.3: Pathway for disease introduction via live swine



12.3.2 Risk factors and existing mitigation measures

The likelihood of CSF or SVD introduction via legal import or trade of live swine depends primarily on the provisions of the harmonized EC import legislation for swine, the efficacy of limiting intra-Community trade from affected regions, and Czech import and trade practices. Risk factors for disease introduction and associated mitigating factors identified in Section 1-11 are summarized below.

Risk factors for disease introduction:

1. CSF – Harmonized EC legislation allows the Czech Republic to import live swine from Switzerland, which APHIS has not evaluated and therefore regards as unknown risk for CSF (*see* Section 7.2.1).
2. CSF – The number of swine traded to the Czech Republic from Germany and Slovakia has increased substantially since accession (*see* Section 7.5).
3. CSF – Outbreaks occurring outside of established control zones within affected Member States where CSF is endemic in wild boar pose a risk to the common and export markets until detected (*see* Section 3.4).
4. CSF – Outbreaks have recurred in several areas of the EU shortly after EC restrictions were lifted, suggesting that 30 days may be an insufficient duration for restrictions (*see* Sections 11.2 and 11.5).
5. CSF and SVD – Veterinary inspection of imported swine at the ports of entry may not detect incubating or subclinical infection (*see* Section 7.2.3).

Factors mitigating the risk of disease introduction:

1. SVD – APHIS considers all of the countries from which EC legislation permits the Czech Republic to import live swine to be free from SVD (*see* Section 7.2.1).
2. CSF and SVD – EC certification requirements for import, transit, or trade in live swine are comprehensive and must be signed by an official veterinarian of the country of origin (*see* Section 7.2.2).
3. CSF and SVD – Veterinary inspection practices at the point of entry would likely detect clinically affected swine (*see* Section 7.2.3).
4. CSF and SVD – Control measures put in place by affected Member States prohibit the sale of live swine from zones under restrictions for CSF or SVD (*see* Section 7.4).

5. CSF and SVD – Isolation, observation, and veterinary inspection of live swine prior to transport increases the likelihood of detecting infected animals, as does spot checks at the point of destination (*see* Sections 7.2.2 and 7.4).
6. CSF – Imported breeding swine over three months of age from Member States that are regionalized for endemic CSF infection in wild boar must be tested within one month of arrival (*see* Section 7.4).

12.3.3 Summary discussion

EC legislation imposes less stringent restrictions on sourcing of imported swine than does U.S. legislation, which could result in a comparatively greater risk of CSF introduction into the Czech Republic and other Member States with which the Czech Republic trades. In addition, the potential exists for trade on the internal common market to introduce CSF from undetected infected herds in unrestricted areas, or from herds in areas released from restrictions too quickly following an outbreak. This is particularly true in light of the substantial increase in swine received from Germany and Slovakia since accession.

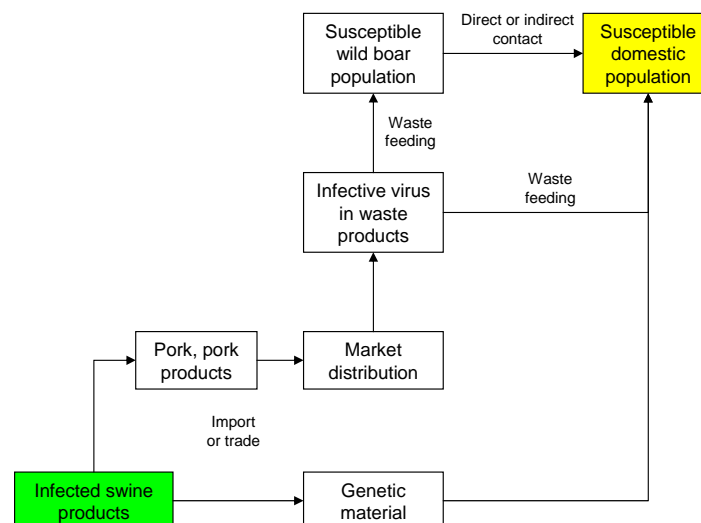
However, the mitigation measures currently in place substantially reduce the risk of introducing CSF into the Czech Republic via imported or traded swine. In addition, the potential for exposure of domestic swine in the Czech Republic is limited by the practices of isolating, observing, and inspecting imported or traded swine at the point of destination. However, additional mitigation measures may be necessary to restrict sourcing of swine for the export process and to prevent commingling with swine from regions that APHIS considers affected with CSF.

12.4 Import, transit, or trade of infected swine products

12.4.1 Central risk issue

Infected swine products such as fresh pork, pork products, semen, embryos, or ova can enter the Czech Republic legally through import or trade, or illegally via smuggling. Figure 12.4 shows the main pathways for introduction of CSF or SVD virus via infected swine products.

Figure 12.4: Pathways for disease introduction via infected swine products



12.4.2 Risk factors and existing mitigation measures

The likelihood of introducing CSF or SVD virus via infected swine products depends primarily on the provisions of the harmonized EC import legislation for swine products, the efficacy of limiting intra-Community trade from affected regions, and Czech import and trade practices.

Risk factors for disease introduction:

1. CSF and SVD – Harmonized EC legislation allows the Czech Republic to import fresh pork and pork products, as well as fresh meat from wild boar, from third countries that APHIS has not evaluated and regards as unknown risk for CSF and SVD (*see* Section 7.2.1).
2. CSF and SVD – Veterinary inspection of imported swine products at the port of entry is unlikely to detect infective virus (*see* Section 7.2.3).
3. CSF – Harmonized EC legislation allows the Czech Republic to import swine semen from Switzerland, which APHIS has not evaluated and regards as unknown risk for CSF (*see* Section 7.2.1).
4. CSF – Outbreaks occurring outside of established control zones within affected Member States where CSF is endemic in wild boar pose a risk to the common and export markets until detection (*see* Section 3.4).
5. CSF – Outbreaks have recurred in several areas of the EU shortly after EC restrictions were lifted, suggesting that 30 days may be an insufficient duration for restrictions (*see* Sections 11.2 and 11.5).
6. CSF – The amount of pork and pork products received from Germany has increased substantially since accession (*see* Section 7.5).

Factors mitigating the risk of disease introduction:

1. CSF and SVD – EC certification requirements for commodities derived from swine and wild boar in third countries are comprehensive and must be signed by an official veterinarian of the country of origin (*see* Section 7.2.2).
2. CSF and SVD – The EC approval process for exporting establishments, including semen collection centers and slaughterhouses, is rigorous and substantially limits exports from approved third countries (*see* Section 7.2.1).
3. CSF and SVD – Control measures put in place by affected Member States effectively prohibit the sale of swine commodities from regions recognized as affected with CSF or SVD (*see* Section 7.4).

12.4.3 Summary discussion

APHIS considers disease introduction via pork and pork products, rather than genetic material, to be the primary risk concern associated with this pathway. Although infected genetic material would most likely result in direct exposure of domestic swine, the strict biosecurity practices required of semen collection centers substantially reduce the risk of disease introduction from this quarter.

Harmonized EC legislation imposes less stringent restrictions on sourcing of swine products than does U.S. legislation, resulting in comparatively greater risk of introducing CSF or SVD into the Czech Republic. However, the approval process for exporting establishments in third countries provides substantial risk mitigation and limits the number of countries actually exporting to the EU.

The potential exists for trade on the internal common market to introduce CSF via commodities from undetected infected herds in unrestricted areas, or from areas released from restrictions too quickly. This is particularly true in light of the substantial increase in pork and pork products received from Germany since accession.

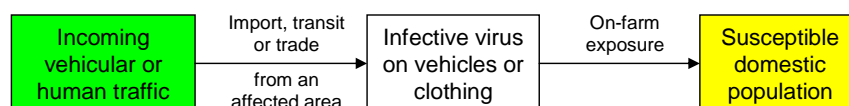
As discussed in the hazard identification section, waste feeding of infected pork or pork products is perhaps the most common cause of outbreaks in domestic swine and wild boar in previously free regions. Noncompliance with the waste feeding ban is most likely on small swine holdings, as is exposure to wild boar infected via waste feeding (*see* Sections 1.5 and 8.1). Biosecurity practices limit the risk of exposure on large confinement operations, which are the most likely source of swine commodities for export to the United States (*see* Section 8.1). However, additional mitigation measures may be necessary to prevent commingling of pork and pork products destined for export with those sourced from an affected country or region.

12.5 Incoming vehicular or human traffic

12.5.1 Central risk issue

CSF or SVD could be introduced into the Czech Republic via incoming vehicular traffic, particularly improperly disinfected live-haul trucks originating in affected regions of Member States. Virus could also be passively introduced by human traffic from affected regions through transmission of live virus on clothing, potentially resulting in on-farm exposure of a domestic swine population (see Figure 12.5).

Figure 12.5: Introduction pathways via vehicular or human traffic



12.5.2 Risk factors and existing risk mitigation measures

The likelihood of introducing CSF or SVD into the Czech Republic via incoming vehicular or human traffic depends primarily on the disease status of neighboring regions and disinfection practices at the point of entry and elsewhere. Risk factors and associated mitigating factors identified in Sections 1-11 are summarized below.

Risk factors for disease introduction:

1. CSF – The Czech Republic shares common land borders with Germany and Slovakia, both of which have endemic CSF infection in wild boar and sporadic outbreaks in domestic swine (*see* Sections 3.1.2 and 3.1.4).

2. SVD – The Czech Republic shares land borders with Poland and Slovakia, which APHIS does not consider free of SVD, although both countries are currently under evaluation (*see* Section 3.2).
3. CSF and SVD – There is considerable local traffic between the Czech Republic and neighboring Member States (*see* Section 7.6).
4. CSF and SVD – No standard disinfection practices are in place for human or vehicular traffic at border crossings without veterinary inspection in the absence of a reported outbreak (*see* Section 7.1.2).

Factors mitigating the risk of disease introduction:

1. SVD – APHIS considers Germany and Austria free of SVD, Slovakia has never reported this disease, and Poland has not reported a case since 1972 (*see* Section 3.2).
2. CSF and SVD – EC legislation requires disinfection of all live-haul trucks after unloading, and in some cases, prior to animal loading (*see* Section 7.1.2).

12.5.3 Summary discussion

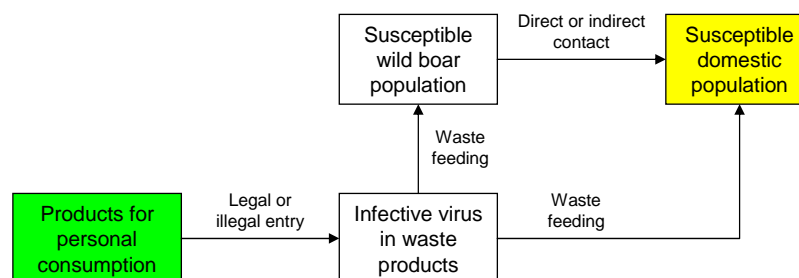
APHIS considers the risk of introducing SVD virus via incoming vehicular or human traffic to be very low. The risk of CSF introduction via this pathway is considerably greater, particularly from affected regions of Germany and Slovakia. Biosecurity practices on most small swine holdings are likely insufficient to protect against virus exposure from this quarter. However, small swine operations in the Czech Republic are also unlikely to contribute products for export to the United States. Existing husbandry and production conditions in the Czech Republic substantially mitigate the export risk to the United States.

12.6 Agricultural commodities for personal consumption

12.6.1 Central risk issue

Infected meat or meat products carried into the Czech Republic by human traffic for personal consumption could introduce CSF or SVD into the country, as shown in Figure 12.6. Such products may be intentionally smuggled into the country or simply missed during Customs inspections at border crossings.

Figure 12.6: Introduction pathways via personal consignments



12.6.2 Risk factors and existing mitigation measures

The likelihood of introducing CSF or SVD via agricultural products for personal consumption depends primarily on EC policies regarding allowable commodities for personal consumption, the extent of passenger traffic from affected regions, and Customs Service inspection, confiscation, and disposal practices at the point of entry.

Risk factors for disease introduction:

1. CSF and SVD – EC legislation permits personal consignments of meat, fluid milk, and meat and milk products from several countries that APHIS has not evaluated and regards as unknown risk for CSF and SVD (*see* Section 7.6).
2. SCF and SVD – Customs Service personnel are not adequately familiar with EC requirements for passenger checks (*see* Section 7.6).
3. CSF – Considerable local traffic occurs from Germany and Slovakia (*see* Section 7.6).

Factors mitigating the risk of disease introduction:

1. CSF and SVD – None of the third countries from which the EC allows personal consignments have reported outbreaks of CSF or SVD in recent years, if ever (*see* Section 7.6).
2. CSF and SVD – The Customs Service inspects a substantial percentage of passenger luggage at the Prague airport, and the inspection process is thorough. Traffic through other border crossing points is also subject to Customs inspection (*see* Sections 7.6 and 7.7.4).
3. CSF and SVD – Signs indicating prohibited items and prominently placed amnesty bins decrease the amount of illegal products unintentionally carried across the border (*see* Section 7.6).

12.6.3 Summary discussion

APHIS considers the risk of introducing CSF into the Czech Republic far greater than SVD, considering the limited worldwide distribution of the latter disease. A risk assessment recently estimated the risk of disease introduction into Great Britain via illegally imported meat to be once in 10 years for CSF and once per billion years for SVD (DEFRA 2004). Infective virus in agricultural commodities for personal consumption could result in direct exposure of susceptible wild boar or domestic swine populations via waste feeding.

Noncompliance with the waste-feeding ban and exposure of domestic swine to infected wild boar are most likely to occur on small swine holdings, which are unlikely to contribute products for export to the United States. Although APHIS considers this to be a higher risk pathway for CSF introduction into the Czech Republic, existing production and biosecurity measures limit the export risk to the United States.

13. Release assessment conclusions

Based on the preceding assessment of the 11 factors specified in 9 CFR 92.2, APHIS has no evidence that CSF or SVD currently exists in domestic swine in the Czech Republic. CSF virus has not been detected in domestic swine since 1997 or in wild boar since 1999, and SVD has never been reported. Based on serological findings, it is likely that one or more CSF strains continue to circulate in the wild boar populations in first- and second-tier districts along the borders with Austria and Slovakia. Based on current production and biosecurity practices, exposure of domestic swine on confinement operations is unlikely. CSF and SVD surveillance measures in domestic swine are commensurate with the risk of introduction of these diseases.

APHIS concludes that the potential for introduction of CSF or SVD into the Czech Republic is greater in some regards than the potential for introduction of these diseases into the United States. For example, the Czech Republic shares common land borders with countries that APHIS regards as regionally affected or unknown risk for these diseases, imports live swine or swine commodities from potentially affected regions, and engages in free trade with other Member States that import live swine or swine commodities from such regions.

The risk profile of the Czech Republic resembles that of the EU-15. APHIS' current regulations recognize an equivalent level of risk across the EU-15 due to harmonized EC legislation and trade on the internal common market. The EU-15 is considered a low-risk region for CSF for the purposes of export to the United States and is subject to the import conditions specified in 9 CFR 94.24 for breeding swine, pork, and pork products, and 9 CFR 98.38 for swine semen. APHIS also recognizes most of the EU-15 as free of SVD but subject to the import restrictions specified in 9 CSF 94.13 based on the existence of common land borders with regions not regarded as free of this disease, and/or import of live swine or swine products from such regions.

Regarding the risk posed by wild boar, APHIS has recognized in previous assessments that a reservoir of CSF infections exists in wild boar in the EU-15 (APHIS 2000; APHIS 2004a). This reservoir is likely to produce continuing CSF outbreaks in domestic swine in the EU. However, in its prior assessments of the CSF situation in the EU-15, APHIS concluded that EC control measures were sufficient to detect and contain any outbreaks that might occur. This assessment verified that the same EC control measures apply in the Czech Republic as in the EU-15 and that the official veterinary services are well trained and equipped to contain and eliminate the outbreak.

APHIS considers the export risk from the Czech Republic to be equivalent to that of the EU-15 with regard to CSF and SVD. Applying provisions of 9 CFR 94.13, 94.24, and 98.38 to the Czech Republic would address the majority of the risk issues discussed in Section 12 and result in a level of risk that is equivalent to that portion of the EU authorized to export breeding swine, swine semen, and fresh pork to the United States.

The text of 9 CFR 94.13, 94.24, and 98.38 is provided in Annex 1. In summary, these CFR sections mitigate the risk associated with less restrictive trade practices by (1) restricting the sourcing of swine for export or slaughter to regions free of CSF and SVD; (2) prohibiting commingling of live swine, pork, or pork products for export with such

commodities from regions not considered free of these diseases; (3) placing certain restrictions on the use of transportation equipment for live swine; and (4) requiring exporting slaughterhouses to be approved by the U.S. Department of Agriculture's Food Safety and Inspection Service. An official veterinarian of the exporting country must certify that these conditions have been met.

The CFR provisions do not directly address the risk of exporting infected live swine or swine commodities during the period between virus incursion and outbreak detection. However, 9 CFR 94.24 and 98.38 substantially mitigate this risk by prohibiting sourcing of swine from a restricted zone established because of detection of CSF in wild boar or a CSF outbreak in domestic swine, as well as for the 6 months following depopulation, cleaning, and disinfection of the last infected premises in the zone. In addition, swine semen collection centers must be approved by the national government of the exporting country according to EC requirements, which provides substantial risk mitigation.

Biosecurity measures and production practices on the large swine confinement operations most likely to export to the United States limit exposure risk for domestic swine in the Czech Republic as discussed in Section 12. Other potential mitigation measures include a mandatory period of observation and/or diagnostic testing prior to live export or slaughtering for export. However, since the results of this assessment indicate that the Czech Republic is currently free of CSF and SVD in domestic swine, these measures are not necessary.

Exposure assessment

An exposure assessment as defined by the OIE describes the biological pathway(s) necessary for exposure of animals and humans in an importing country to the hazards released from a given risk source, and estimates the probability of the exposure(s) occurring (OIE 2005a). APHIS' regulatory authority is limited to animal health, however, so potential risks to animals are the primary focus of this evaluation.

APHIS considers that the most likely pathway of exposure of domestic livestock to CSF and SVD viruses in pork and pork products is through feeding of contaminated food waste to swine (CEAH 2001). Other exposure pathways are more direct and include contact with imported infected live animals or contact with infected genetic material.

1. Waste feeding to susceptible swine

1.3 Waste-feeding practices in the United States

The likelihood of exposure of susceptible species to virus-infected meat was evaluated in previous APHIS studies. In 1995, APHIS conducted a pathway analysis to estimate the likelihood of exposing swine to infected waste (APHIS 1995). The analysis included two pathways for exposure of swine to contaminated waste; namely, exposure associated with illegal household imports, and exposure associated with legal imports. The latter is the exposure pathway that would be applicable to importing meat or meat products from the Czech Republic. With 95% confidence, APHIS estimated that 0.023% or less of plate and manufacturing waste would be inadequately processed prior to feeding to swine (APHIS 1995). Based on this fraction, less than 1 part in 4,300 (reciprocal of 0.023%) of imported meat is likely to be fed to swine as inadequately cooked waste.

APHIS conducted a survey in 2001 of the U.S. swine waste-feeding sector to update a similar study done in 1994 (APHIS 2002). Based on this survey, APHIS estimated that the proportion of plate and manufacturing waste fed to swine diminished by about 50% between 1994 and 2001 due to a significant decrease in the number of waste-feeding premises. The study also found that:

1. Several more U.S. States prohibited feeding food wastes to swine;
2. The number of waste-feeding premises in the continental United States decreased by 40.5% from 1994-2001, and in Hawaii and Puerto Rico decreased by 37.5% and 52.3%, respectively; and
3. Institutions and restaurants provide nearly 90% of all plate waste fed to swine.

APHIS considers that prohibiting the feeding of unprocessed plate waste to swine has further contributed to the reduction of waste-feeding to swine. Waste-feeder operations must be licensed and inspected regularly by U.S. Department of Agriculture inspectors (9 CFR 166). The licensing process requires that producers adequately cook the waste fed to swine using methods designed to destroy foreign animal disease agents.

Based on the 1995 estimate that a very small proportion of food waste is inadequately processed prior to feeding to swine, and the substantial reduction in waste-feeding operations in recent years, APHIS concludes that the likelihood of exposure of susceptible swine to CSF or SVD viruses through inadequately processed food waste is low. Based on the results of the release assessment, APHIS further regards the probability

of exposure of susceptible swine to these viruses through inadequately cooked infected meat from the Czech Republic as low.

2. Imported live animals

The likelihood of exposure of susceptible species to infected live swine was evaluated by briefly reviewing virus persistence and shedding in live swine, as well as U.S. standard import requirements for this species. This exposure assessment focuses on breeding animals because transportation costs are prohibitive for export of other live swine (e.g. feeder pigs) to the United States from EU Member States, and because U.S. regulations only allow import of breeding swine from the EU-15. APHIS considers exposure of U.S. swine to illegally imported infected live swine from the Czech Republic to be highly unlikely.

The survival period of CSF virus within live swine ranges from 1 week to greater than 6 months depending on various host-pathogen factors. Although SVD virus is not known to cause persistent infection, a large percentage of infections are subclinical and therefore may remain undetected without diagnostic testing prior to export.

Consequently, APHIS considers this potential pathway for disease introduction to have high unmitigated risk. The risk is partially mitigated by current U.S. regulations requiring a minimum quarantine period of 15 days for all imported swine (9 CFR 93.510), which increases the probability of disease detection. Based on the results of the release assessment, APHIS considers the likelihood of exposure of U.S. domestic swine to CSF or SVD virus via live swine from the Czech Republic to be low. With the mitigation measures for live swine described in 9 CFR 94.24, which further limit the sourcing of swine for export (see footnote on page 29), the probability of exposure of susceptible U.S. swine to CSF virus via infected swine from the Czech Republic is very low.

3. Imported genetic material

Genetic material has been implicated in the introduction of foreign animal diseases into susceptible populations, as well as the spread of established disease epidemics over considerable distances. For example, two semen collection centers became infected during the course of the 1997-1998 CSF epidemic in the Netherlands (Hennecken et al 2000). Potentially contaminated semen was distributed to 1,680 swine herds over the course of 5 weeks, during which the disease remained undetected in the donor boars. Although investigators concluded that only 36 farms had been infected through artificial insemination, all suspect farms were subject to quarantine and testing, resulting in a tremendous expenditure of resources.

Survival of CSF virus in semen has been estimated in experimental studies to be 12-72 hours at 20°C but ranges from 1 month to several years at 4°C or below (Floegel et al 2000). Survival in embryos and ova is unknown (Floegel et al 2000; Glossup and Cameron 2002). Survival of SVD virus in genetic material is possible but is not considered to be a primary mode of transmission (OIE 2005b).

APHIS considers the unmitigated likelihood of exposure of domestic swine to CSF virus in infected semen to be high. However, based on the results of the release assessment, APHIS considers the likelihood of exposure of susceptible animals to CSF virus via

infected semen from the Czech Republic to be low. With the mitigation measures for swine semen described in 9 CFR 98.38 (see footnote on page 29), the probability of exposure of susceptible swine to CSF or SVD viruses via infected semen from the Czech Republic is very low.

Consequence assessment

A consequence assessment describes the biologic and economic consequences of introducing the hazards under consideration into the United States. This consequence assessment addresses both direct and indirect consequences as recommended by the OIE (OIE 2005a).

The magnitude of the biologic and economic consequences following an introduction of CSF or SVD virus would depend on the location of the introduction; the virus serotype introduced; the rate of virus spread and whether other environmental conditions at the introduction site that might facilitate this spread; the ability to detect the disease rapidly; swine demographics and movement patterns; and the ease of employing eradication procedures. In addition, depending on the extent of export of swine and swine products, trade restrictions imposed by trading partners may result in severe economic consequences.

Direct consequences include effects of the disease on animal health and the subsequent production losses, the total costs of control and eradication, the effect on the environment, and public health consequences. Indirect consequences include impacts on international trade and associated domestic consequences.

1. Effects on animal health and production

1.1 Classical swine fever

CSF infection may take an acute or a chronic course. The severity of the disease depends largely on the age of the animal and virulence of the viral strain, with young animals usually more severely affected than older animals. In older breeding pigs the course of infection is often mild or even subclinical, whereas mortality rates may reach 90% in young pigs (Moennig 2000). Low virulence strains may manifest primarily as poor reproductive performance and birth of piglets with neurologic defects.

1.2 Swine vesicular disease

SVD is typically a transient vesicular disease of pigs. The virus causes essentially no mortality, and infected pigs generally recover within one week (up to three weeks). Some strains produce only mild clinical symptoms or are asymptomatic (OIE 2005b). Morbidity rates may be low throughout a whole herd but high in certain pens.

2. Control and eradication costs

The overall cost of control and eradication depends on the mitigation or policy option chosen to control and eradicate the disease. Potential costs include disease control measures such as imposing quarantine measures and movement controls, direct costs related to stamping out of affected and other herds, indemnity payments, vaccination costs, surveillance and laboratory testing, etc. For disease-free countries like the United States that have a substantial export market for livestock and livestock products, the preferred option for control and eradication has traditionally been to stamp out infected herds without the use of vaccine.

The U.S. policy for most significant foreign animal disease emergencies is to follow strict quarantine measures and stamping out of infected and contact herds with ongoing assessment for the need for and implementation of strategic vaccination. Available data do not allow quantification of the number of herds/farms that would be affected if one of these diseases were introduced. Nevertheless, the cost of control, eradication and compensation is likely to be significant.

2.1 Classical swine fever

Since there have been no CSF outbreaks in the United States from which economic estimates can be derived, estimates of economic effects in other countries are provided as illustrations. Saatkamp et al (2000) reviewed the economic aspects of control of small and large CSF outbreaks in the EU from 1990-1997. For the largest outbreak, involving 429 herds over 14 months, the cost of removal of affected swine was 426.9 million Euros, slaughter for welfare purposes cost 1.2 billion Euros, and program operational costs were 134.3 million Euros. Overall, the outbreak cost pig producers 712.4 million Euros, the national government 230.5 million Euros, and the EU 807.8 million Euros. The total cost of smaller outbreaks ranged from 10.9 million Euros (8 affected herds over 2 months) to 208.7 million Euros (113 affected herds over 10 months) (Saatkamp et al 2000). Approximately 10 million pigs were destroyed during the course of the outbreak, primarily for welfare reasons (overcrowding or overweight) (Stegeman et al 2000).

Garner et al (2001) estimated the potential economic impact of CSF on the pig industry of Australia using a stochastic modeling process. The model estimated a loss in gross income of 28-37% for the pig industry in the affected region, and a 9-11% loss in gross income for the national pig industry.

2.2 Swine vesicular disease

Little information exists on the cost of control and eradication of SVD in a previously free region. SVD virus generally does not spread as quickly as CSF virus; even on infected premises, spread from one pen to another may not occur in the absence of a common open drainage system or of frequent movement of pigs between pens (Lin and Kitching 2000). However, a SVD outbreak may not be detected for weeks or even months due to the frequently mild nature of the disease, allowing ample time for spread to other swine establishments. In addition, the virus is extraordinarily stable in the environment, which could lead to disease recurrence on previously infected farms.

In the absence of specific data on the cost of control and eradication, APHIS assumes a baseline cost similar to that of a small- to medium-sized CSF outbreaks (see above).

3. Effect on the environment

Environmental effects have been considered under all applicable environmental review laws in force in the United States. These are considered in a separate, but related, environmental assessment conducted for certain regions of the EU (APHIS 2003). The environmental assessment complies with the National Environmental Policy Act (NEPA) and implementing regulations (NEPA 1969).

4. Effect on public health

Although public health consequences are not issues under APHIS' regulatory authority, the subject is briefly addressed in this assessment. Direct public health consequences are insubstantial because the occurrence of CSF or SVD infection in humans is quite rare. In fact, the number of cases reported is so small when compared with the number of persons exposed to these viruses that the World Health Organization generally does not consider CSF or SVD viruses to be a threat to humans.

Perhaps more importantly, a substantial foreign animal disease outbreak can result in severe psychosocial effects on farmers and farming communities (Anonymous 2004). Farmers and their families can suffer from grief over losing animals, in some cases blood lines kept over many generations, as well as loss of control over their lives due to movement restrictions, disruptions in community life, and short- and long-term stress over their financial future.

5. Indirect consequences

In addition to the direct costs of CSF or SVD introduction, impacts on international trade and related domestic consequences need to be considered. Export losses due to restrictions imposed by trade partners on animals and products susceptible to these diseases could run into billions of U.S. dollars. The value of U.S. exports of pork and pork products, which would be immediately lost if an outbreak of one of these diseases occurred, was an estimated 1.3 billion USD in 2003 (FAS 2005). The impact of an outbreak of a foreign animal disease on the rural and regional economic viability, including businesses reliant on livestock revenue, could also be substantial.

Indirect economic losses to U.S. firms that support export markets for live animals and animal products could also be substantial. In the longer term, if trade restrictions persisted and alternative export markets did not develop, the U.S. swine production sector could contract, allowing other supplying countries to establish trade relationships in the absence of U.S. supply.

Risk Estimation

Risk estimation consists of integrating the results from the release assessment, exposure assessment, and consequence assessment to produce overall measures of risk associated with the hazards identified at the outset (OIE 2005a). Thus, risk estimation takes into account the whole risk pathway from hazard identified to the unwanted event.

APHIS concluded from the release assessment that there is no evidence that CSF or SVD currently exist in domestic swine in the Czech Republic. APHIS considers the risk potential for introduction of these hazards from the Czech Republic into the United States via exported live swine and swine commodities to be low. In keeping with previous analyses, APHIS also concludes that there is an equivalent low level of risk across all of the EU regions that are unaffected by CSF and SVD. If mitigation measures for the Czech Republic are implemented that are equivalent to those specified for other EU Member States in 9 CFR 94.13, 94.24, and 98.38, the risk would be reduced even further.

APHIS concluded from the exposure assessment that the probability of exposure of susceptible U.S. livestock to CSF or SVD viruses via pork or pork products, live swine, or swine genetic material from the Czech Republic is low. Applying risk mitigation measures similar to those described in 9 CFR 94.24 for live swine, pork, and pork products, and 9 CFR 98.38 for swine semen, would further reduce the likelihood of exposure to viable virus.

Conversely, APHIS concludes that the animal health and economic consequences of a CSF or SVD outbreak in the United States would be severe. Although control and eradication measures would be costly, the major economic impact would likely result from export trade losses.

In summary, a CSF or SVD outbreak in the United States would be likely to have severe animal health and economic consequences; however, APHIS considers the risk of infected live swine or swine commodities entering the United States from the Czech Republic and exposing U.S. domestic swine to be low. This risk is reduced to very low if the Czech Republic is subject to the same mitigations measures as are specified for other EU Member States in 9 CFR 94.13, 94.24, and 98.38.

Annexes

Annex 1: Text of Title 9 *Code of Federal Regulations* 94.13, 94.24, and 98.38.

9 CFR 94.13: Restrictions on importation of pork or pork products from specified regions

Austria, the Bahamas, Belgium, Bulgaria, Chile, Denmark, France, Germany, Hungary, Luxembourg, the Netherlands, Portugal, Republic of Ireland, Spain, Switzerland, the United Kingdom (England, Scotland, Wales, the Isle of Man, and Northern Ireland), Yugoslavia, and the Regions in Italy of Friuli, Liguria, Marche, and Valle d'Aosta are declared free of swine vesicular disease in Sec. 94.12(a) of this part.

These regions either supplement their national pork supply by the importation of fresh (chilled or frozen) meat of animals from regions where swine vesicular disease is considered to exist, have a common border with such regions, or have trade practices that are less restrictive than are acceptable to the United States. Thus, the pork or pork products produced in such regions may be commingled with fresh (chilled or frozen) meat of animals from a region where swine vesicular disease is considered to exist, resulting in an undue risk of swine vesicular disease introduction into the United States. Therefore, pork or pork products and ship's stores, airplane meals, and baggage containing such pork, other than those articles regulated under part 95 or part 96 of this chapter, produced in such regions shall not be brought into the United States unless the following requirements are met in addition to other applicable requirements of part 327 of this title:

(a) All such pork or pork products, except those treated in accordance with Sec. 94.12(b)(1)(i) of this part, shall have been prepared only in inspected establishments that are eligible to have their products imported into the United States under the Federal Meat Inspection Act (21 U.S.C. 601 et seq.) and under Sec. 327.2 of this title and shall be accompanied by the foreign meat inspection certificate required by Sec. 327.4 of this title. Upon arrival of the pork or pork products in the United States, the foreign meat inspection certificate must be presented to an authorized inspector at the port of arrival.

(b) Unless such pork or pork products are treated according to one of the procedures described in Sec. 94.12(b) of this part, the pork or pork products must be accompanied by an additional certificate issued by a full-time salaried veterinary official of the agency in the national government responsible for the health of the animals within that region. Upon arrival of the pork or pork products in the United States, the certificate must be presented to an authorized inspector at the port of arrival. The certificate shall state the name and official establishment number of the establishment where the swine involved were slaughtered and the pork was processed. The certificate shall also state that:

(1) The slaughtering establishment is not permitted to receive animals that originated in, or have ever been in a region listed in Sec. 94.12(a) as a region in which swine vesicular disease is considered to exist;

(2) The slaughtering establishment is not permitted to receive pork derived from swine which originated in such a region or pork from swine from a swine vesicular disease free region which has been transported through a region where swine vesicular disease is considered to exist except pork which was transported in containers sealed with serially numbered seals of the National Government of a region of origin listed in Sec. 94.12 as a region considered free of the disease.

(3) The pork has been processed, stored, and transported to the means of conveyance that will bring the article to the United States in a manner that precludes its being commingled or otherwise coming in contact with pork or pork products that have not been handled in accordance with the requirements of this section.

9 CFR 94.24: Restrictions on the importation of pork, pork products, and swine from the EU-15.

(a) Pork and pork products. In addition to meeting all other applicable provisions of this part, fresh pork and pork products imported from the EU-15 must meet the following conditions:

(1) The pork or pork products must not have been derived from swine that were in any of the regions described in paragraphs (a)(1)(i) through (a)(1)(iii) of this section during the periods described, unless the swine were slaughtered after the periods described:

(i) Any region when the region was classified in §§ 94.9(a) and 94.10(a) as one in which classical swine fever is known to exist, except for the EU-15;

(ii) In a restricted zone in the EU-15 established because of an outbreak of classical swine fever in domestic swine, from the time of the outbreak until the designation of the zone as a restricted zone is removed by the competent veterinary authority of an EU-15 Member State or until 6 months following depopulation of the swine on affected premises in the restricted zone and the cleaning and disinfection of the last affected premises in the zone, whichever is later; or

(iii) In a restricted zone in the EU-15 established because of the detection of classical swine fever in wild boar, before the designation of the zone as a restricted zone is removed by the competent veterinary authority of an EU-15 Member State.

(2) The pork and pork products must not have been commingled with pork or pork products derived from swine that were in any of the regions or zones described in paragraphs (a)(1)(i) through (a)(1)(iii) of this section at any time during the periods described, unless the swine were slaughtered after the periods described. Additionally, the pork and pork products must not have been derived from swine that were commingled with swine that were in any of the regions or zones described in paragraphs (a)(1)(i) through (a)(1)(iii) of this section at any time during the periods described, unless the swine were slaughtered after the periods described.

(3) The swine from which the pork or pork products were derived must not have transited any region or zone described in paragraph (a)(1)(i) through (a)(1)(iii) of this section during the periods described, unless moved directly through the region or zone in a sealed means of conveyance with the seal determined to be intact upon arrival at the point of destination, or unless the swine were slaughtered after the periods described.

(4) The pork and pork products must be accompanied by a certificate issued by an official of the competent veterinary authority of the EU-15 Member State who is authorized to issue the foreign meat inspection certificate required by § 327.4 of this title, stating that the applicable provisions of paragraphs (a)(1) through (a)(3) of this section have been met.

(b) Live swine. In addition to meeting all other applicable provisions of this title, live swine imported from the EU-15 must meet the following conditions:

(1) The swine must be breeding swine;

(2) The swine must not have been in any of the following regions or zones at any time during the periods described in paragraphs (b)(2)(i) through (b)(2)(iii) of this section:

(i) Any region when the region was classified in §§ 94.9(a) and 94.10(a) as one in which classical swine fever is known to exist, except for the EU-15, unless the swine are exported to the United States after APHIS removes its classification of the region as one in which classical swine fever is known to exist;

(ii) In a restricted zone in the EU-15 established because of an outbreak of classical swine fever in domestic swine, unless the swine are exported after the designation of the zone as a restricted zone is removed by the competent veterinary authority of an EU-15 Member State or after 6 months following depopulation of the swine on affected premises in the restricted zone and the cleaning and disinfection of the last affected premises in the zone, whichever is later; or

(iii) In a restricted zone in the EU-15 established because of the detection of classical swine fever in wild boar, unless the swine are exported after the designation of the zone as a restricted zone is removed by the competent veterinary authority of an EU-15 Member State;

(3) The swine must not have been commingled with swine that have at any time been in any of the regions described in paragraphs (b)(1)(i) through (b)(1)(iii) of this section during the periods described, unless the swine are exported after the periods described;

(3) The swine must not have transited any region or zone described in paragraph (b)(2) of this section during the periods described, unless moved directly through the region or zone in a sealed means of conveyance with the seal determined to be intact upon arrival at the point of destination, or unless the swine are exported after the periods described;

(4) No equipment or materials used in transporting the swine may have previously been used for transporting swine that do not meet the requirements of this section, unless the equipment and materials have first been cleaned and disinfected; and

(5) The swine must be accompanied by a certificate issued by a salaried veterinary officer of the competent veterinary authority of the EU-15 Member State, stating that the conditions of paragraphs (b)(1) through (b)(4) of this section have been met.

(c) The certificates required by paragraphs (a)(4) and (b)(5) of this section must be presented by the importer to an authorized inspector at the port of arrival, upon arrival of the swine, pork, or pork products at the port.

9 CFR 98.38: Restrictions on the importation of swine semen from the EU-15.

In addition to meeting all other applicable provisions of this part, swine semen imported from the EU-15 must meet the following conditions, except as noted in paragraph (h) of this section with regard to swine semen imported from Denmark, Finland, the Republic of Ireland, Sweden, or the United Kingdom:

(a) The semen must come from a semen collection center approved for export by the competent veterinary authority of the EU-15 Member State;

(b) The semen must not have been collected from a donor boar that was in any of the regions or zones described in paragraphs (b)(1) or (b)(2) of this section at any time during the periods described, unless the semen was collected after the periods described:

(1) Any region when the region was classified in §§ 94.9(a) and 94.10(a) of this chapter as one in which classical swine fever is known to exist, except for the EU-15; or

(2) During the following time periods in any restricted zone in the EU-15:

(i) In a restricted zone in the EU-15 established because of an outbreak of classical swine fever in domestic swine, from the time of the outbreak until the designation of the zone as a restricted zone is removed by the competent veterinary authority of an EU-15 Member State or until 6 months following depopulation of the swine on affected premises in the restricted zone and the cleaning and disinfection of the last affected premises in the zone, whichever is later; or

(ii) In a restricted zone established because of the detection of classical swine fever in wild boar, before the designation of the zone as a restricted zone is removed by the competent veterinary authority of the EU-15 Member State.

(c) The semen must not have been collected from a donor boar that was commingled with swine that at any time were in any of the regions or zones described in paragraphs (b)(1) or (b)(2) of this section, unless the semen was collected after the periods described;

(d) The semen must not have been collected from a donor boar that transited any region or zone described in paragraphs (b)(1) and (b)(2) of this section during the periods described, unless the donor boar was moved directly through the region or zone in a sealed means of conveyance with the seal determined to be intact upon arrival at the point of destination, or unless the semen was collected after the periods described;

(e) The donor boar must be held in isolation for at least 30 days prior to entering the semen collection center;

(f) No more than 30 days prior to being held in isolation as required by paragraph (c) of this section, the donor boar must be tested with negative results with a classical swine fever test approved by the Office International des Epizooties (World Organization for Animal Health);

(g) No equipment or materials used in transporting the donor boar from the farm of origin to the semen collection center may have been used previously for transporting swine that do not meet the requirements of this section, unless such equipment or materials had first been cleaned and disinfected;

(h) Except for semen collected from swine in Denmark, Finland, the Republic of Ireland, Sweden, or the United Kingdom, before the semen is exported to the United States, the donor boar must be held at the semen collection center and observed by the center veterinarian for at least 40 days following collection of the semen, and, along with all other swine at the semen collection center, exhibit no clinical signs of classical swine fever; and

(i) The semen must be accompanied to the United States by a certificate issued by a salaried veterinary officer of the competent veterinary authority of the EU-15 Member State, stating that the provisions of paragraphs (a) through (f) of this section have been met.

Annex 2: Age distribution of seropositive wild boar 2000 – 2005.**Figure 2A: Age distribution of seropositive wild boar in 2000**

District	Total	Piglets	Yearlings	Boars	Sows	Other
Břeclav	25	3	5	1	3	13
Hodonín	6	1	4	0	0	1
Vyškov	16	5	6	0	0	5
Uherské Hradiště	14	2	7	0	1	4
Kroměříž	14	2	7	1	3	1
Znojmo	11	1	2	1	0	7
Jihlava	13	4	3	2	0	4
Žďár nad Sázavou	2	1	0	0	0	1
Třebíč	3	0	0	0	0	3
Jindřichův Hradec	1	1	0	0	0	0
Zlín	47	1	20	15	7	4
Nový Jičín	1	0	1	0	0	0
Opava	1	0	0	0	0	1
Vsetín	6	2	3	1	0	0
Total	160	23	58	21	14	44

Figure 2B: Age distribution of seropositive wild boar in 2001

District	Total	Piglets	Yearlings	Boars	Sows	Other
Břeclav	17	5	5	2	0	5
Hodonín	2	0	2	0	0	0
Vyškov	7	3	1	0	3	0
Uherské Hradiště	6	1	1	1	3	0
Kroměříž	11	0	5	0	1	5
Znojmo	10	1	0	3	2	4
Jihlava	9	2	5	0	1	1
Žďár nad Sázavou	1	0	0	0	0	1
Třebíč	1	0	1	0	0	0
Zlín	25	3	7	5	7	3
Frýdek Místek	1	1	0	0	0	0
Vsetín	4	0	3	0	0	1
Total	94	16	30	11	17	20

Figure 2C: Age distribution of seropositive wild boar in 2002

District	Total	Piglets	Yearlings	Boars	Sows	Other
Břeclav	14	3	2	1	8	0
Hodonín	6	0	5	0	1	0
Vyškov	5	2	3	0	0	0
Uherské Hradiště	3	0	1	1	1	0
Kroměříž	2	0	1	0	0	1
Brno-venkov	1	1	0	0	0	0
Třebíč	2	1	0	0	0	1
Zlín	16	1	11	1	3	0
Jindřichův Hradec	1	1	0	0	0	0
Vsetín	1	1	0	0	0	0
Total	51	10	23	3	13	2

Figure 2D: Age distribution of seropositive wild boar in 2003

District	Total	Piglets	Yearlings	Boars	Sows	Other
Břeclav	21	9	7	2	1	2
Hodonín	6	0	2	0	0	4
Vyškov	2	2	0	0	0	0
Uherské Hradiště	3	1	1	0	0	1
Jihlava	2	1	1	0	0	0
Brno-venkov	2	1	0	0	0	1
Třebíč	1	1	0	0	0	0
Zlín	14	5	8	1	0	0
Jindřichův Hradec	3	1	2	0	0	0
Znojmo	1	0	0	0	0	1
Total	55	21	21	3	1	9

Figure 2E: Age distribution of seropositive wild boar in 2004

District	Total	Piglets	Yearlings	Boars	Sows	Other
Břeclav	1	0	1	0	0	0
Hodonín	4	0	3	0	1	0
Vyškov	1	0	0	0	1	0
Uherské Hradiště	1	0	1	0	0	0
Rychnov n/Kněžnou	1	1	0	0	0	0
Zlín	2	0	2	0	0	0
Jindřichův Hradec	1	0	1	0	0	0
Total	11	1	8	0	2	0

Figure 2F: Age distribution of seropositive wild boar in 2005

District	Total	Piglets	Yearlings	Boars	Sows	Other
Břeclav	3	1	1	1	0	0
Zlín	11	2	9	0	0	0
Jindřichův Hradec	3	1	2	0	0	0
Uherské Hradiště	8	4	3	1	0	0
Hodonín	1	0	1	0	0	0
Total	26	8	16	2	0	0

Annex 3: Import and export data for 1999 – 2004.**Figure 3A: Live swine imports 1999 – 2004 (GTA 2006)**

Country	1999	2000	2001	2002	2003	2004
World	2,588	1,060	284	1,939	438	9,229
EU-15	2,588	1,060	284	1,939	438	8,384
-Austria	1	1	18	120	9	2
-Belgium	0	0	203	0	0	0
-Denmark	0	8	8	0	5	4
-France	244	64	20	1,765	376	1,578
-Germany	2,140	918	35	54	48	4,458
-Netherlands	0	0	0	0	0	1,039
-Sweden	5	0	0	0	0	3
-United Kingdom	198	69	0	0	0	1,300
EU-10	0	0	0	0	0	845
-Slovakia	0	0	0	0	0	845

Figure 3B: Live swine exports 1999 – 2004 (GTA 2006)

Country	1999	2000	2001	2002	2003	2004
World	56,473	22,495	23,279	65,639	64,612	186,984
EU-15	791	490	496	1,151	138	41,020
-Austria	311	0	0	160	0	12,403
-Belgium	0	0	69	0	0	733
-France	0	340	0	0	0	0
-Germany	2	0	180	619	138	27,884
-Greece	0	0	177	0	0	0
-Italy	0	0	70	0	0	0
-Spain	480	150	0	372	0	0
EU-10	48,520	21,020	22,608	39,731	20,540	122,151
-Hungary	1,037	0	378	9,122	2,663	77,339
-Latvia	0	0	120	0	0	0
-Lithuania	0	0	65	0	0	0
-Poland	0	0	0	0	0	168
-Slovakia	47,163	21,020	22,045	30,609	17,877	44,644
-Slovenia	320	0	0	0	0	0
Other	7,160	985	175	24,757	43,934	23,813
-Bosnia and Herzegovina	6,267	0	0	700	1,856	2,107
-Bulgaria	0	0	0	454	1,054	0
-Croatia	543	981	0	0	24,092	12,762
-Macedonia	0	0	175	160	0	0
-Romania	350	0	0	23,443	16,932	7,641
-Russia	0	4	0	0	0	1,303

Figure 3C: Imports of fresh, chilled, and frozen pork 1999 – 2004 (GTA 2006)

Country	1999	2000	2001	2002	2003	2004
World	16,377	13,526	15,718	24,173	28,457	62,451
EU-15	15,353	13,485	15,599	21,689	21,649	53,519
-Austria	1,785	856	342	291	451	4,237
-Belgium	1172	1,280	996	1,005	1,568	1,507
-Denmark	2,712	4,724	4,295	5,376	5,206	7,997
-France	819	327	511	3,256	2,265	4,280
-Germany	7,071	3820	7,926	9,340	10,290	27,874
-Ireland	21	82	0	21	42	43
-Italy	501	1,346	867	524	66	1,655
-Netherlands	213	224	106	640	227	2,791
-Spain	621	703	536	1,236	1,534	3,047
-Sweden	0	0	0	0	0	21
-United Kingdom	438	123	20	0	0	67
EU-10	874	41	119	2,484	6,808	8,932
-Cyprus	0	0	0	0	0	237
-Hungary	873	40	20	2,299	6,061	3,881
-Poland	1	1	1	0	696	4,178
-Slovakia	0	0	98	185	50	636
-Slovenia	0	0	0	0	1	0
Other	150	0	0	0	0	0
-Australia	0	0	0	0	0	0
-Canada	48	0	0	0	0	0
-New Zealand	0	0	0	0	0	0
-Norway	102	0	0	0	0	0

Figure 3D: Exports of fresh, frozen, and chilled pork 1999 – 2004 (GTA 2006)

Country	1999	2000	2001	2002	2003	2004
World	5792	4053	8155	16118	9147	13659
EU-15	156	268	995	289	222	1414
-Austria	102	50	93	71	63	556
-Belgium	2	2	0	0	0	0
-Denmark	0	76	252	104	3	216
-France	19	0	20	1	23	0
-Germany	33	6	192	63	77	509
-Greece	0	0	0	0	0	6
-Italy	0	31	131	33	0	106
-Netherlands	0	62	278	17	35	21
-Spain	0	41	29	0	21	0
EU-10	5029	3440	5503	12699	7160	10574
-Estonia	0	484	554	502	41	118
-Hungary	0	0	0	1803	427	1980
-Poland	955	21	0	0	0	842
-Slovakia	3974	2935	4949	10284	6612	7624
-Slovenia	100	0	0	110	80	10
Other	607	345	1657	3130	1765	1671
-Bosnia and Herzegovina	0	0	0	0	0	34
-Bulgaria	111	0	118	479	0	60
-Croatia	0	0	11	454	521	80
-Georgia	0	0	19	0	0	0
-Macedonia	0	0	0	244	0	0
-Moldova	0	0	0	0	0	9
-Romania	450	345	1475	1933	1105	1330
-Russia	45	0	26	20	0	97
-Serbia and Montenegro	0	0	0	0	139	0
-Switzerland	0	0	8	0	0	0
-Ukraine	1	0	0	0	0	61

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Commission Decision 94/63/EEC of 31 January 1994 drawing up a provisional list of third countries from which Member States authorize imports of semen, ova, and embryos of the ovine, caprine and equine species, ova and embryos of the porcine species (as amended).

Commission Decision 97/365/EC of 26 March 1997 drawing up provisional lists of third country establishments from which the Member States authorize imports of products prepared from meat of bovine animals, swine, equidae and sheep and goats (as amended).

Commission Decision 98/139/EC of 4 February 1998 laying down certain detailed rules concerning on-the-spot checks carried out in the veterinary field by Commission experts in the Member States.

Commission Decision 1999/608/EC of 10 September 1999 amending Annexes of Council Directive 90/429/EEC laying down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the porcine species.

Commission Decision 2000/428/EC of 4 July 2000 establishing diagnostic procedures, sampling methods and criteria for the evaluation of the results of laboratory tests for the confirmation and differential diagnosis of swine vesicular disease.

Commission Decision 2000/678/EC of 23 October 2000 laying down detailed rules for registration of holding in national databases for porcine animals as foreseen by Council Directive 64/432/EEC.

Commission Decision 2001/881/EC of 7 December 2001 drawing up a list of border inspection posts agreed for veterinary checks on animals and animal products from third countries and updating the detailed rules concerning the checks to be carried out by the experts of the Commission (as amended).

Commission Decision 2001/812/EC of 21 November 2001 laying down the requirements for the approval of border inspection posts responsible for veterinary checks on products introduced into the community from third countries.

Commission Decision 2002/106/EC of 1 February 2002 approving a Diagnostic Manual establishing diagnostic procedures, sampling methods and criteria for evaluation of the laboratory tests for the confirmation of classical swine fever (as amended).

Commission Decision 2002/613/EC of 19 July 2002 laying down the importation conditions of semen of domestic animals of the porcine species (as amended).

Commission Decision 2003/526/EC of 18 July 2003 concerning protection measures relating to classical swine fever in Belgium, France, Germany and Luxembourg (as amended).

Commission Decision 2004/212/EC of 6 January 2004 on Community health conditions on imports of animals and fresh meat including minced meat from third countries and amending Decisions 79/542/EEC, 2000/572/EC and 2000/585/EC.

Commission Decision 2004/431/EC of 29 April 2004 approving certain contingency plans for the control of classical swine fever (as amended).

Commission Decision 2004/639/EC of 19 July 2002 laying down the importation condition of semen of domestic animals of the porcine species (as amended).

Commission Regulation (EEC) No. 2454/93 of 2 July 1993 laying down provisions for the implementation of Council Regulation (EEC) No. 2913/92 establishing the Community Customs Code (as amended).

Commission Regulation (EC) No. 745/2004 of 16 April 2004 laying down measures with regard to imports of products of animals origin for personal consumption.

Council Decision 79/542/EEC of 21 December 1976 drawing up a list of third countries or part of third countries, and laying down animal and public health and veterinary certification condition, for importation into the Community of certain animals and their fresh meat (as amended).

Council Decision 90/424/EEC of 26 June 1990 on expenditures in the veterinary field (as amended).

Council Directive 82/894/EEC of 21 December 1982 on the notification of animal diseases within the Community (as amended).

Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra- Community trade in certain live animals and products with a view to the completion of the internal market (as amended).

Council Directive 90/429/EEC of 26 June 1990 laying down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the porcine species (as amended).

Council Directive 91/496/EEC of 15 July 1991 laying down the principles governing the organization of veterinary checks on animals entering the Community from third countries and amending Directives 89/662/EEC, 90/425/EEC and 90/675/EEC (as amended).

Council Directive 92/119/EEC of 17 December 1992 introducing general Community measures for the control of certain animal diseases and specific measures relating to swine vesicular disease (as amended).

Council Directive 96/43/EEC of 26 June 1996 amending and consolidating Council Directive 85/73/EEC in order to ensure financing of veterinary inspections and controls on live animals and certain animal products and amending Directives 90/675/EEC and 91/496/EEC.

Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organization of veterinary checks on products entering the Community from third countries (as amended).

Council Directive 2001/89/EC of 23 October 2001 on Community measures for the control of classical swine fever (as amended).

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